

## Exhibit 1-A

**UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF VIRGINIA  
ALEXANDRIA DIVISION**

JANINE ALI,

Plaintiff,

v.

ELI LILLY AND COMPANY, an Indiana  
corporation,

Defendant.

**CASE NO. 1:14-CV-01615-GBL-TRJ**

**PLAINTIFF'S FIRST SET OF REQUESTS FOR PRODUCTION OF DOCUMENTS**

**PROPOUNDING PARTY:** Plaintiff, Janine Ali

**RESPONDING PARTY:** Defendant Eli Lilly and Company

**SET NO.:** ONE

Plaintiff Janine Ali ("PLAINTIFF"), by and through her attorneys, and pursuant to Federal Rule of Civil Procedure 26 and 34, does hereby serve written requests upon Defendant Eli Lilly and Company ("Lilly") to produce for inspection and reproduction the following documents and things specified below at the offices of BAUM, HEDLUND, ARISTEI & GOLDMAN, P.C., 12100 Wilshire Boulevard, Suite 950, Los Angeles, CA 90025, in accordance with the following definitions and instructions and within thirty (30) days of service.

**DEFINITIONS**

The following definitions apply to each request below and are incorporated therein:

1. "ALL" means "any and all" and the word "any" means "any and all."
2. The term "CYMBALTA" means duloxetine hydrochloride, including any other name or trademark under which it is sold, domestically *or* abroad, marketed or produced,

including products sold, marketed, or produced by others if they do so with your permission, at your request, at your direction, with your acquiescence, and/or if you gain any benefit from their sales, marketing, or distribution.

3. The term “COMMUNICATION” means and refers to every method and manner of transmitting or receiving data, opinions, thoughts, inquiries, representations and other information, whether orally, in writing, electronically, or otherwise, between two or more persons or entities. Communications include drafts and other written information intended for communicating to another person, even if not ultimately transmitted to or received by another person.

4. The terms “CONCERNING,” “RELATING,” and/or “REGARDING” mean containing, alluding to, responding to, commenting upon, discussing, explaining, mentioning, analyzing, constituting, memorializing, comprising, repeating, incorporating, confirming, listing, evidencing, setting forth, summarizing, or characterizing, either directly or indirectly, in whole or in part.

5. The term “DEAE” means Discontinuation Emergent Adverse Event, and refers to any possible side effects or symptoms relating to discontinuing, withdrawing, or tapering from the use, consumption, or treatment with Cymbalta.

6. The term “WITHDRAWAL” includes discontinuation or tapering, as well as DEAEs, withdrawal symptoms, and any side effects of withdrawing, discontinuing, or tapering from CYMBALTA.

7. The term “DOCUMENT” shall have the broadest meaning possible under Rule 34 of the Federal Rules of Civil Procedure and includes all originals and drafts, in any and all languages, of any nature whatsoever, in your possession, custody or control, regardless of where

located, and include, but are not limited to, letters, correspondence, logs, drafts, contracts, prospective contracts, agreements, reports, records, studies, surveys, resolutions, tabulations, notes, summaries, memoranda, Electronically Stored Information (“ESI”), electronic mail (“email”), calendar or diary entries, handwritten notes, working papers, work sheets, spread sheets, diagrams, minutes of meetings, agendas, bulletins, periodicals, circulars, advertisements, notices, announcements, invoices, statements, checks (front and back), bank statements, ledgers, orders, vouchers, instructions, drawings, charts, graphs, manuals, brochures, pamphlets, schedules, telegrams, teletypes, photographs, audio tapes, voice-mail messages, videotapes, electronic recordings, facsimile transmissions, and information of whatever kind either stored on computers, including computer disks, hard drives and other media, or contained in any computer or information retrieval devices.

8. The terms “ELI LILLY,” “LILLY,” “YOU” or “YOUR” refer to Eli LILLY and Company, its respective officers, directors, employees, representatives, subsidiaries, and affiliates thereof, as well as all persons acting for, on behalf of, or in concert with Eli LILLY and Company’s behalf, including agents, attorneys, accountants, and investigators.

9. The term “FDA” means the United States Food & Drug Administration.

10. The term “INCLUDING” means “including, but not limited to.”

11. The term “LABEL” refers to the official prescribing information for the drug, including but not limited to the product insert and medication guides approved by the FDA or other foreign regulatory bodies.

12. The term “MEDICAL PROFESSIONAL” includes healthcare providers, prescribing doctors, non-prescribing doctors, physicians, pharmacists, nurses, and other individuals who provide healthcare services.

13. The term “PERAHIA ARTICLE” refers to David G. Perahia, *et al.*, *Symptoms Following Abrupt Discontinuation of Duloxetine Treatment in Patients with Major Depressive Disorder*, 89 J. Affective Disorders 207-12 (2005).

14. The term “SNRI” means serotonin norepinephrine reuptake inhibitor.

15. The term “SSRI” means selective serotonin reuptake inhibitor.

16. The use of the terms “or,” “and,” and “and/or” should be construed conjunctively and disjunctively for the broadest possible meaning.

17. The term “person” or “people” includes individuals, corporations, partnerships, associations, and other bodies and entities, as well as their representatives, agents, employees and attorneys.

18. The terms “research,” “study,” or “analysis,” when used as a noun mean and refer to any research, analysis, study, report, evaluation or assessment. The term research when used as a verb means to research, analyze, study, report, evaluate, or assess.

19. The term “use” means to “employ something for a purpose,” “to do something habitually,” “to consume something,” “to manipulate,” “to benefit from,” as well as to allow others to “use,” or acquiesce in others’ “use.”

20. The singular use of any term or phrase includes its plural, and the plural of any term or phrase includes its singular.

21. The use of any tense of any verb shall also include within its meaning all other tenses of that verb.

### **INSTRUCTIONS**

1. You must serve your responses and any objections within 30 days after being served the requests.

2. Each paragraph and subparagraph of each request should be construed independently, and not be referenced to any other paragraph or subparagraph of this request for purposes of limitation.

3. Pursuant to the Fed. R. Civ. P. 26(e), these requests are continuing in nature, so as to require a supplemental response to correct any incomplete or incorrect answer based on information you may become aware of between the time of your initial response and the time of trial.

4. In responding to these requests, you shall respond based on information in your possession, custody, or control, including (by way of illustration only and not limited to) information in the possession, custody, or control of your affiliates, subsidiaries, or subcontractors, your present or former attorneys, accountants, directors, officers, partners, employees, other representatives and agents, independent contractors over which or whom you have or have had control, and any other persons acting on your behalf.

5. Notwithstanding the assertion of any objection to production, any documents as to which an objection is raised that also contain non-objectionable matter that is relevant and material to a request herein must be produced, but that portion of the documents for which the objection is asserted may be redacted, provided that the material redacted is listed in the privilege log.

6. If you claim that the attorney-client privilege, or any other privilege, doctrine or reason for withholding a document is applicable, please set forth in writing and with your response to this Request: (1) the date of the document; (2) the type of document; (3) the subject matter of the document; (4) the name, employment and title of each person who prepared or received the document or any copy thereof; and (5) the basis for the claim of privilege or other

ground for withholding the document. If you claim only part of the document is privileged or otherwise need not be produced, please produce the remaining part of the document. In the case of attorney work-product privilege, you must also identify the litigation for which the work-product was prepared.

7. If any document to be produced has been lost, discarded, transferred to another person or entity, destroyed, or otherwise disposed of, please set forth in writing: (1) the date, name and subject matter of the document; (2) the name, employment and title of each person who prepared, received, reviewed, or had custody, possession, or control of the document; (3) all persons with knowledge of the contents or any portion of the contents of the document; (4) the previous location of the document; (5) the date of disposal or transfer of the document; (6) the reason for disposal or transfer of the document; and, if applicable, (7) the manner of disposal of the document; or, if applicable, (8) the names and addresses of the transferees of the document.

8. For the convenience of the Court and the parties, Plaintiffs request that each request be quoted in full immediately preceding the answer.

9. Whenever a reference to a business entity appears, the reference shall mean the business entity, its affiliated entities, partnerships, divisions, subdivisions, directors, officers, employees, agents, clients, or other representatives of affiliated third parties.

10. Unless specified by the request, there is no time limitation to any of these requests.

11. As provided by Federal Rule of Civil Procedure Rule 34(b)(2)(E)(iii), please produce all electronically stored information in their native electronic format with all metadata preserved in a \*.DAT file format. "Electronically stored information" includes the full scope of that term as contemplated by Federal Rule of Civil Procedure Rule 34, and refers to all computer

or electronically stored or generated data and information, and shall include all attachments to the enclosures with any requested item, to which they are attached or with which they are enclosed, and all drafts thereof. “Electronically stored information” includes, but is not limited to, all information stored in any format on any storage media, including for example, but not limited to: hard disks, floppy disks, optical disks, flash memory devices, and magnetic tape, whether fixed, portable, or removable. The format of “electronically stored information” includes, for example, but is not limited to: word processing documents, electronic spreadsheets, electronic presentation documents, email messages, image files, sound files, material or information stored in a database, or accessible from a database, of whatever description. “Electronically stored information” also includes all associated metadata that is routinely maintained or saved, which includes for example, but is not limited to document title or name, file name, date and time of creation, date and time of last edit, identity of author, identity of owner, identities of editors, identities of recipients, changes, history of changes, email header information, and email routing information.) Please produce all metadata in a \*.DAT file format. If a document contains a single redaction, please provide the appropriate metadata for the remainder of the document, notwithstanding the redactions and the information provided separately as part of a privilege log.

12. For the convenience of the parties and to reduce production costs, please produce all DOCUMENTS which exist only in hardcopy, i.e., cannot be produced in the electronic format discussed above, form in an electronic format such as a \*.PDF format or equivalent.

13. In response to each request, please specifically reference which Bates numbered pages are responsive to *that* request. Generalized reference to categories of documents is the equivalent of no response at all. If no DOCUMENTS are responsive, please indicate such. If



you are not responding to a request or any portion therein, please indicate such.

## **REQUESTS FOR PRODUCTION**

### **I. FDA DOCUMENTS**

#### **REQUEST FOR PRODUCTION NO. 1:**

Please produce the Electronic Common Technical Document (eCTD) or equivalent electronic submission for all CYMBALTA indications, whether that indication was approved or denied, including but not limited to: Major Depressive Disorder (MDD), Generalized Anxiety Disorder (GAD), Neuropathic Pain from Diabetes, Chronic Pain, Chronic Musculoskeletal Pain, Fibromyalgia, MDD Maintenance, GAD Maintenance, and Stress Urinary Incontinence (SUI).

#### **REQUEST FOR PRODUCTION NO. 2:**

Please produce the Summary Basis of Approval for CYMBALTA for the following indications: Major Depressive Disorder (MDD), Generalized Anxiety Disorder (GAD), Neuropathic Pain from Diabetes, Chronic Pain, Chronic Musculoskeletal Pain, Fibromyalgia, MDD Maintenance, and GAD Maintenance.

#### **REQUEST FOR PRODUCTION NO. 3:**

Please produce all Periodic Safety Updates regarding CYMBALTA for the following indications: Major Depressive Disorder (MDD), Generalized Anxiety Disorder (GAD), Neuropathic Pain from Diabetes, Chronic Pain, Chronic Musculoskeletal Pain, Fibromyalgia, MDD Maintenance, and GAD Maintenance.

#### **REQUEST FOR PRODUCTION NO. 4:**

Please produce all Annual Safety Updates regarding CYMBALTA for the following indications: Major Depressive Disorder (MDD), Generalized Anxiety Disorder (GAD), Neuropathic Pain from Diabetes, Chronic Pain, Chronic Musculoskeletal Pain, Fibromyalgia,

MDD Maintenance, and GAD Maintenance.

**REQUEST FOR PRODUCTION NO. 5:**

Please produce the electronic Investigational New Drug (“IND”) file for CYMBALTA.

**REQUEST FOR PRODUCTION NO. 6:**

Please produce all warning letters sent to YOU from the FDA regarding CYMBALTA.

**REQUEST FOR PRODUCTION NO. 7:**

Please produce YOUR responses to all warning letters sent to YOU from the FDA regarding CYMBALTA.

**REQUEST FOR PRODUCTION NO. 8:**

Please produce the transcript of any FDA Advisory Committee meetings regarding CYMBALTA for any indication.

**REQUEST FOR PRODUCTION NO. 9:**

Please produce any DOCUMENTS submitted to the FDA as part of any Advisory Committee meeting related to CYMBALTA.

**REQUEST FOR PRODUCTION NO. 10:**

Please produce any and all Form 483 and/or Warning Letters that YOU received from the FDA related to CYMBALTA.

**REQUEST FOR PRODUCTION NO. 11:**

Please produce YOUR responses to all Form 483 and/or Warning Letters that YOU received from the FDA related to CYMBALTA.

**REQUEST FOR PRODUCTION NO. 12:**

Please produce all DOCUMENTS reflecting any settlements, agreements, resolutions, fines, sanctions and/or additional regulatory actions that arose as a result of the Form 483 and/or

Warning Letters that YOU received from the FDA related to CYMBALTA.

**REQUEST FOR PRODUCTION NO. 13:**

Please produce all DOCUMENTS related to any COMMUNICATIONS with the FDA about CYMBALTA containing any of the following terms (or any derivative term): DEAE, withdrawal, discontinuation or discontinuing, dependence, habit-forming, addiction, quitting, tapering, brain zaps, electric shock, down regulation, half-life, missed dose, “greater than or equal to,” Perahia, Rosenbaum, or Schatzberg.

**REQUEST FOR PRODUCTION NO. 14:**

Please produce all DOCUMENTS related to any COMMUNICATIONS with the FDA about Prozac or fluoxetine containing any of the following terms (or any derivative term): DEAE, withdrawal, discontinuation or discontinuing, dependence, habit-forming, addiction, quitting, tapering, brain zaps, electric shock, down regulation, half-life, missed dose, “greater than or equal to,” Perahia, Rosenbaum, or Schatzberg.

**REQUEST FOR PRODUCTION NO. 15:**

Please produce all DOCUMENTS related to any COMMUNICATIONS with the FDA about Zyprexa or olanzapine containing any of the following terms (or any derivative term): DEAE, withdrawal, discontinuation or discontinuing, dependence, habit-forming, addiction, quitting, tapering, brain zaps, electric shock, down regulation, half-life, missed dose, “greater than or equal to,” Perahia, Rosenbaum, or Schatzberg.

**REQUEST FOR PRODUCTION NO. 16:**

Please produce all DOCUMENTS reflecting COMMUNICATIONS with the FDA about the section of the US LABEL titled “Discontinuation of Treatment with Cymbalta.”

**REQUEST FOR PRODUCTION NO. 17:**

Please produce all DOCUMENTS reflecting COMMUNICATIONS with the FDA about the sections of the US LABEL titled “Dosage and Administration” or “Medication Administration” or “Information for Patients” (depending on year).

**REQUEST FOR PRODUCTION NO. 18:**

Please produce all DOCUMENTS that reflect COMMUNICATIONS between LILLY and the FDA concerning LILLY’s Medical Information Letters, or similar letters, concerning the potential risk of withdrawal or discontinuation from CYMBALTA.

**REQUEST FOR PRODUCTION NO. 19:**

Please produce all COMMUNICATIONS between YOU and the FDA concerning the half-life of CYMBALTA.

**REQUEST FOR PRODUCTION NO. 20:**

Please produce all COMMUNICATIONS between YOU and the FDA concerning the enteric coating of CYMBALTA.

**REQUEST FOR PRODUCTION NO. 21:**

Please produce a copy of each FDA-approved version of the package insert for CYMBALTA used by LILLY since it began marketing CYMBALTA in the United States.

**REQUEST FOR PRODUCTION NO. 22:**

Please produce a copy of each version of the LABEL for CYMBALTA in each foreign country wherein CYMBALTA was approved for marketing in that country.

**REQUEST FOR PRODUCTION NO. 23:**

Please produce the electronic Adverse Event Reporting database for CYMBALTA.

## **II. INTERNAL COMMUNICATIONS ABOUT CYMBALTA**

### **REQUEST FOR PRODUCTION NO. 24:**

Please produce all DOCUMENTS reflecting LILLY's internal COMMUNICATIONS and/or deliberations concerning the section of the US CYMBALTA LABEL titled "Discontinuation of Treatment with Cymbalta," including not limited to all emails, memorandums, drafts, comments, edits, redlines, or discussions about those edits of those sections of the US CYMBALTA LABEL.

### **REQUEST FOR PRODUCTION NO. 25:**

Please produce all DOCUMENTS reflecting LILLY's internal COMMUNICATIONS and/or deliberations concerning the section of the US CYMBALTA LABEL titled "Dosage and Administration" or "Medication Administration" or "Information for Patients" (depending on year), including not limited to all emails, memorandums, drafts, comments, edits, redlines, or discussions about those edits of the that section of the US CYMBALTA LABEL.

### **REQUEST FOR PRODUCTION NO. 26:**

Please produce all DOCUMENTS reflecting LILLY's internal COMMUNICATIONS and/or deliberations concerning the following sentences in the US CYMBALTA LABEL as it was approved in 2004, including but not limited to all emails, memorandums, drafts, comments, edits, redlines, or discussions about those edits: "Duloxetine should be swallowed whole and should not be chewed or crushed, nor should the contents be sprinkled on food or mixed with liquids. All of these might affect the enteric coating."

### **REQUEST FOR PRODUCTION NO. 27:**

Please produce all DOCUMENTS that reflect LILLY's reason for changing the US LABEL concerning "Discontinuation of Treatment with Cymbalta" in 2008 from "the following

symptoms occurred at a rate greater than or equal to 2%” to “the following symptoms occurred at a rate greater than or equal to 1%.”

**REQUEST FOR PRODUCTION NO. 28:**

Please produce all DOCUMENTS that reflect LILLY’s reason for adding to the 2009 US CYMBALTA LABEL “or tapered” in the context of “Following abrupt ... discontinuation ...” in the section titled “Discontinuation of Treatment with Cymbalta.”

**REQUEST FOR PRODUCTION NO. 29:**

Please produce all DOCUMENTS that reflect LILLY’s reason for changing the US CYMBALTA LABEL in 2012 from “the following symptoms occurred at a rate greater than or equal to 1%” to “at 1% or greater” in the section titled “Discontinuation of Treatment with Cymbalta.”

**REQUEST FOR PRODUCTION NO. 30:**

Please produce all DOCUMENTS that reflect LILLY’s reason for creating CYMBALTA as capsules containing enteric-coated pellets of duloxetine hydrochloride.

**REQUEST FOR PRODUCTION NO. 31:**

Please produce all DOCUMENTS reflecting LILLY’s internal COMMUNICATIONS and/or deliberations concerning the design of CYMBALTA as enteric-coated pellets contained within a capsule.

**REQUEST FOR PRODUCTION NO. 32:**

Please produce all DOCUMENTS reflecting LILLY’s internal COMMUNICATIONS and/or deliberations concerning the development of a dosage of CYMBALTA below 20mg.

**REQUEST FOR PRODUCTION NO. 33:**

Please produce all DOCUMENTS reflecting LILLY’s internal COMMUNICATIONS

and/or deliberations concerning the development of CYMBALTA as a scored tablet.

**REQUEST FOR PRODUCTION NO. 34:**

Please produce all memoranda, presentations, and/or reports, whether prepared internally or provided to LILLY by a third-party, that discuss, in any way, CYMBALTA and WITHDRAWAL.

**REQUEST FOR PRODUCTION NO. 35:**

Please produce all electronic mail ("email") for the individuals identified in Interrogatory Nos. 1 & 3, whether internal or external and whether on LILLY's current computer operating system, on individual employees' laptop computers, or archive systems, which contain at least one of the following terms:

**Cy!, dulo!, Aricclaim, Xeristar, Yentreve, Duzela, Dulane, Cymgen, Prozac, Fluox!, Paxil, Parox!, Zoloft, Sertra!, Celexa, Citalop!, Lexapro, Escitalop!, Effexor, venlafa!, Pristiq, desvenlafax!, milnacipr!, levomilnacipr!, SSRI!, SNRI!, or anti!,**

*and* at least one of the following terms:

**DEAE!, discon!, withd!, taper!, cold w/1turkey, addict!, habit!, paresth!, zap!, electric w/4 shock, dizz!, Rosenbaum, Schatzberg, Glenmullen, half-life, "missed dose," downregu!, "greater than or equal to," Perahia, enteric, pellets, "delayed release."**

**REQUEST FOR PRODUCTION NO. 36:**

Please produce all DOCUMENTS that reflect LILLY's internal COMMUNICATIONS and/or deliberations concerning any and all letters used by LILLY to respond to inquiries regarding CYMBALTA and DEAEs, discontinuation, withdrawal, dependence, or addiction.

**REQUEST FOR PRODUCTION NO. 37:**

Please produce all DOCUMENTS that reflect LILLY's internal COMMUNICATIONS

and/or deliberations concerning any of LILLY's Medical Information Letters, or similar letters, concerning the potential risk of withdrawal or discontinuation from CYMBALTA.

**REQUEST FOR PRODUCTION NO. 38:**

Please produce all minutes of meetings of any LILLY committee, working group, department, board, etc. where CYMBALTA and WITHDRAWAL were discussed.

**REQUEST FOR PRODUCTION NO. 39:**

Please produce all DOCUMENTS that reflect LILLY's internal COMMUNICATIONS and/or deliberations concerning why the rate of WITHDRAWAL reflected in the PERAHIA article was not included in the US LABEL.

**REQUEST FOR PRODUCTION NO. 40:**

Please produce all DOCUMENTS that reflect LILLY's internal COMMUNICATIONS and/or deliberations concerning why the rate of WITHDRAWAL reflected in the PERAHIA article was included in the European LABEL.

**REQUEST FOR PRODUCTION NO. 41:**

Please produce all DOCUMENTS that reflect LILLY's internal COMMUNICATIONS concerning discontinuation or withdrawal symptoms upon discontinuation of Effexor, including but not limited to any discussion concerning the language contained in the US Effexor LABEL concerning WITHDRAWAL.

**III. COMMUNICATIONS WITH MEDICAL PROFESSIONALS**

**REQUEST FOR PRODUCTION NO. 42:**

Please produce any "Dear Healthcare Professional" or similar letters to doctors, pharmacies or other groups, organizations about CYMBALTA.



**REQUEST FOR PRODUCTION NO. 43:**

Please produce all DOCUMENTS that contain a record or description of COMMUNICATIONS to LILLY from MEDICAL PROFESSIONALS or the public, including but not limited to call logs, inquiring about CYMBALTA that mention DEAEs, withdrawal, discontinuation or discontinuing, dependence, habit-forming, addiction, quitting, tapering, brain zaps, electric shock, down regulation, half-life (or any related or derivative terms).

**REQUEST FOR PRODUCTION NO. 44:**

Please produce any and all letters used by LILLY to respond to inquiries regarding CYMBALTA and DEAEs, discontinuation, withdrawal, dependence, or addiction.

**REQUEST FOR PRODUCTION NO. 45:**

Please produce a copy of each and every version of LILLY's "Medical Information Letter" or similar letters to doctors, pharmacies or other groups, organizations or entities discussing the potential risk of withdrawal or discontinuation from CYMBALTA.

**REQUEST FOR PRODUCTION NO. 46:**

Please produce all DOCUMENTS that identify MEDICAL PROFESSIONALS to whom LILLY sent a Medical Information Letter concerning the potential risk of withdrawal or discontinuation from CYMBALTA (e.g., an Excel spreadsheet or Access spreadsheet).

**REQUEST FOR PRODUCTION NO. 47:**

Please produce any and all DOCUMENTS that reflect each inquiry from a MEDICAL PROFESSIONAL concerning Cymbalta and withdrawal or discontinuation, including but not limited to written letters, telephone calls, online requests, sales representative relay.

**IV. MEDICAL LITERATURE AND CONTINUING MEDICAL EDUCATION**

**REQUEST FOR PRODUCTION NO. 48:**

Please produce all publication plans for CYMBALTA, whether prepared internally or by a third-party.

**REQUEST FOR PRODUCTION NO. 49:**

Please produce all DOCUMENTS reflecting LILLY's involvement in the drafting, editing, and publication the PERAHIA ARTICLE, including but not limited to all email communications, article drafts, and publication plans relating to the PERAHIA ARTICLE.

**REQUEST FOR PRODUCTION NO. 50:**

Please produce the study protocol and final study reports for each of the CYMBALTA trials discussed in the PERAHIA ARTICLE.

**REQUEST FOR PRODUCTION NO. 51:**

Please produce the raw data, including but not limited to the case report forms for each of the CYMBALTA trials discussed in the PERAHIA ARTICLE.

**REQUEST FOR PRODUCTION NO. 52:**

Please produce all DOCUMENTS reflecting the amount of compensation given to the authors of the PERAHIA ARTICLE, including but not limited to non-listed authors in the final publication.

**REQUEST FOR PRODUCTION NO. 53:**

Please produce a copy of the articles identified in Interrogatories Nos. 18 &19.

**REQUEST FOR PRODUCTION NO. 54:**

Please produce all DOCUMENTS reflecting LILLY's involvement in the drafting, editing, and publication of those articles identified in Interrogatories Nos. 18 &19.

**REQUEST FOR PRODUCTION NO. 55:**

Please produce all DOCUMENTS reflecting the amount of compensation given to the authors of those articles identified in Interrogatories Nos. 18 &19, including but not limited to compensation associated with the article's publication. In lieu of producing these documents, Plaintiff would accept an Excel chart listing each author and the total amount of compensation received by that author by LILLY, by year.

**REQUEST FOR PRODUCTION NO. 56:**

Please produce all DOCUMENTS reflecting any communications between LILLY and the authors of the articles identified in Interrogatories Nos. 18 &19 concerning discontinuation or withdrawal symptoms upon discontinuation of any SSRI or SNRI, including but not limited to CYMBALTA, Effexor, Prozac, Paxil and Zoloft.

**REQUEST FOR PRODUCTION NO. 57:**

Please produce all DOCUMENTS reflecting any COMMUNICATIONS between LILLY and Mario Fava concerning discontinuation or withdrawal symptoms upon discontinuation of any SSRI or SNRI, including but not limited to CYMBALTA, Effexor, Prozac, Paxil and Zoloft.

**REQUEST FOR PRODUCTION NO. 58:**

Please produce all DOCUMENTS reflecting any COMMUNICATIONS between LILLY and Jerrold Rosenbaum concerning discontinuation or withdrawal symptoms upon discontinuation of any SSRI or SNRI, including but not limited to CYMBALTA, Effexor, Prozac, Paxil and Zoloft.

**REQUEST FOR PRODUCTION NO. 59:**

Please produce all DOCUMENTS reflecting any COMMUNICATIONS between LILLY and Peter Haddad concerning discontinuation or withdrawal symptoms upon discontinuation of

any SSRI or SNRI, including but not limited to CYMBALTA, Effexor, Prozac, Paxil and Zoloft.

**REQUEST FOR PRODUCTION NO. 60:**

Please produce all DOCUMENTS reflecting any communications between LILLY and Alan Schatzberg concerning discontinuation or withdrawal symptoms upon discontinuation of any SSRI or SNRI, including but not limited to CYMBALTA, Effexor, Prozac, Paxil and Zoloft.

**REQUEST FOR PRODUCTION NO. 61:**

Please produce all CYMBALTA clinical trials wherein DEAEs or withdrawal symptoms were measured, noted, calculated, or where data concerning DEAEs or withdrawal was obtained, regardless of whether measuring DEAEs or withdrawal symptoms was part of the trial's original protocol. Please note this request is not limited in time (i.e., pre-approval or post-approval), geography (i.e., location of the study or clinical trial), type (i.e., placebo-controlled, active-controlled, or open), authorship (i.e., LILLY-sponsored or conducted by a third-party), or whether the trial was FDA-sanctioned. This request seeks all DEAE or withdrawal clinical data within LILLY's possession.

**REQUEST FOR PRODUCTION NO. 62:**

Please produce any presentations, PowerPoint presentations, memoranda, product brochures / marketing materials, and/or audio/video recordings, used by LILLY with regard to CYMBALTA that mention the potential risk of withdrawal or discontinuation from CYMBALTA.

**REQUEST FOR PRODUCTION NO. 63:**

Please produce all Continuing Medical Education ("CME") presentations or programs, including those DOCUMENTS given to attendees of CMEs, sponsored or created by YOU that mention DEAEs, withdrawal, discontinuation, dependence or addiction, whether related to

CYMBALTA or not, including but not limited to presentations that reference Prozac / fluoxetine and/or Effexor / venlafaxine.

**REQUEST FOR PRODUCTION NO. 64:**

Please produce DOCUMENTS which list, in whatever interval those lists were compiled, key opinion leaders / thought leaders related to CYMBALTA.

**REQUEST FOR PRODUCTION NO. 65:**

Please produce all DOCUMENTS reflecting any agreement with a key opinion leader / thought leader related to CYMBALTA.

**REQUEST FOR PRODUCTION NO. 66:**

Please produce all DOCUMENTS reflecting any compensation given to a key opinion leader / thought leader related to CYMBALTA.

**V. SALES AND MARKETING**

**REQUEST FOR PRODUCTION NO. 67:**

Please produce all television commercials for CYMBALTA.

**REQUEST FOR PRODUCTION NO. 68:**

Please produce all radio commercials for CYMBALTA.

**REQUEST FOR PRODUCTION NO. 69:**

Please produce all advertisements in magazines for CYMBALTA.

**REQUEST FOR PRODUCTION NO. 70:**

Please produce all advertisements on the internet for CYMBALTA.

**REQUEST FOR PRODUCTION NO. 71:**

Please produce all press releases ever issued by LILLY with regard to CYMBALTA.

**REQUEST FOR PRODUCTION NO. 72:**

Please produce all COMMUNICATIONS with WebMD regarding CYMBALTA.

**REQUEST FOR PRODUCTION NO. 73:**

Please produce every marketing plan, including all drafts, for CYMBALTA, regardless of whether that plan was prepared internally or by a third-party.

**REQUEST FOR PRODUCTION NO. 74:**

Please produce any report or DOCUMENT reflecting the effectiveness of LILLY's marketing campaigns for CYMBALTA.

**REQUEST FOR PRODUCTION NO. 75:**

Please produce every business plan, including all drafts, for CYMBALTA, regardless of whether that plan was prepared internally or by a third-party.

**REQUEST FOR PRODUCTION NO. 76:**

Please produce every launch plan, including all drafts, for CYMBALTA, regardless of whether that plan was prepared internally or by a third-party.

**REQUEST FOR PRODUCTION NO. 77:**

Please produce all COMMUNICATIONS between LILLY and any third-party marketing company or consultant concerning CYMBALTA's direct-to-consumer marketing that discusses, in any way, WITHDRAWAL.

**REQUEST FOR PRODUCTION NO. 78:**

Please produce all COMMUNICATIONS between LILLY and any third-party marketing company or consultant concerning CYMBALTA's direct-to-consumer marketing that discusses, in any way, once-a-day versus twice-a-day dosing.

**REQUEST FOR PRODUCTION NO. 79:**

Please produce all DOCUMENTS reflecting any contract or agreement between LILLY and a third-party company or consultant related to CYMBALTA's direct-to-consumer marketing.

**REQUEST FOR PRODUCTION NO. 80:**

Please produce all market surveys and focus group results / summaries for CYMBALTA.

**REQUEST FOR PRODUCTION NO. 81:**

Please produce all versions of materials and DOCUMENTS, including but not limited to videos or audio recordings, used to train LILLY pharmaceutical representatives about CYMBALTA.

**REQUEST FOR PRODUCTION NO. 82:**

Please produce DOCUMENTS reflecting LILLY's policies and practices regarding communicating with a MEDICAL PROFESSIONAL by a LILLY pharmaceutical representative.

**REQUEST FOR PRODUCTION NO. 83:**

Please produce exemplars of samples of CYMBALTA that were left with MEDICAL PROFESSIONALS by LILLY pharmaceutical representatives.

**REQUEST FOR PRODUCTION NO. 84:**

Please produce all marketing or promotional materials used with MEDICAL PROFESSIONALS by LILLY pharmaceutical representatives, regardless of whether that material was left with the MEDICAL PROFESSIONAL or not.

**REQUEST FOR PRODUCTION NO. 85:**

Please produce DOCUMENTS reflecting LILLY's policies and practices regarding the showing of medical journal articles to MEDICAL PROFESSIONALS by a LILLY

pharmaceutical representative.

**REQUEST FOR PRODUCTION NO. 86:**

Please produce all medical journal articles used by LILLY pharmaceutical representatives to promote CYMBALTA.

**REQUEST FOR PRODUCTION NO. 87:**

Please produce all DOCUMENTS that reflect COMMUNICATIONS between LILLY and the media about CYMBALTA and WITHDRAWAL.

**VI. CLIENT-SPECIFIC REQUESTS**

**REQUEST FOR PRODUCTION NO. 88:**

Please produce all DOCUMENTS reflecting any COMMUNICATION between LILLY and the following:

- Dr. Navera R. Ahmad  
Virginia Hospital Center  
1701 N. George Mason Drive  
Arlington, VA 22205  
(703) 525-3069
- Dr. Thonia Hafez Gab-Allah (retired)  
(571) 232-1309
- Dr. Jayasree Patla  
Alexandria Healthcare  
6303 Little River Turnpike, Suite 160  
Alexandria, VA 22312  
(703) 658-2650

**REQUEST FOR PRODUCTION NO. 89:**

Please produce the custodial file, including but not limited to employment agreements, termination agreements, performance reviews, self-reviews, W-2s, and bonus amounts, for each pharmaceutical representative who called upon the following:

- Dr. Navera R. Ahmad  
Virginia Hospital Center  
1701 N. George Mason Drive



Arlington, VA 22205  
(703) 525-3069

- Dr. Thonia Hafez Gab-Allah (retired)  
(571) 232-1309
- Dr. Jayasree Patla  
Alexandria Healthcare  
6303 Little River Turnpike, Suite 160  
Alexandria, VA 22312  
(703) 658-2650

**REQUEST FOR PRODUCTION NO. 90:**

Please produce all records, entries, or other data from YOUR pharmaceutical representative database, or any other electronic database used to track sales calls to physicians, regarding each and every sales call made to following:

- Dr. Navera R. Ahmad  
Virginia Hospital Center  
1701 N. George Mason Drive  
Arlington, VA 22205  
(703) 525-3069
- Dr. Thonia Hafez Gab-Allah (retired)  
(571) 232-1309
- Dr. Jayasree Patla  
Alexandria Healthcare  
6303 Little River Turnpike, Suite 160  
Alexandria, VA 22312  
(703) 658-2650

**REQUEST FOR PRODUCTION NO. 91:**

Please produce all DOCUMENTS reflecting any compensation, gifts, payments, honoraria, or consulting fees given by LILLY to the following:

- Dr. Navera R. Ahmad  
Virginia Hospital Center  
1701 N. George Mason Drive  
Arlington, VA 22205  
(703) 525-3069
- Dr. Thonia Hafez Gab-Allah (retired)  
(571) 232-1309

- Dr. Jayasree Patla  
Alexandria Healthcare  
6303 Little River Turnpike, Suite 160  
Alexandria, VA 22312  
(703) 658-2650

**REQUEST FOR PRODUCTION NO. 92:**

Please produce any written agreements, contracts, liability releases, or other legal documents that have been drafted and/or executed between LILLY or any third-party representing LILLY and the following:

- Dr. Navera R. Ahmad  
Virginia Hospital Center  
1701 N. George Mason Drive  
Arlington, VA 22205  
(703) 525-3069
- Dr. Thonia Hafez Gab-Allah (retired)  
(571) 232-1309
- Dr. Jayasree Patla  
Alexandria Healthcare  
6303 Little River Turnpike, Suite 160  
Alexandria, VA 22312  
(703) 658-2650

**REQUEST FOR PRODUCTION NO. 93:**

Please produce all DOCUMENTS, including but not limited to marketing materials, brochures, sales aids, “slim jims,” “skiffs,” clinical trials / medical journal articles, PowerPoint presentations, etc., that were given or shown by LILLY pharmaceutical representatives to the following:

- Dr. Navera R. Ahmad  
Virginia Hospital Center  
1701 N. George Mason Drive  
Arlington, VA 22205  
(703) 525-3069
- Dr. Thonia Hafez Gab-Allah (retired)  
(571) 232-1309

- Dr. Jayasree Patla  
Alexandria Healthcare  
6303 Little River Turnpike, Suite 160  
Alexandria, VA 22312  
(703) 658-2650

**REQUEST FOR PRODUCTION NO. 94:**

Please produce all DOCUMENTS reflecting participation in any LILLY-sponsored educational or sales program involving CYMBALTA by the following:

- Dr. Navera R. Ahmad  
Virginia Hospital Center  
1701 N. George Mason Drive  
Arlington, VA 22205  
(703) 525-3069
- Dr. Thonia Hafez Gab-Allah (retired)  
(571) 232-1309
- Dr. Jayasree Patla  
Alexandria Healthcare  
6303 Little River Turnpike, Suite 160  
Alexandria, VA 22312  
(703) 658-2650

**REQUEST FOR PRODUCTION NO. 95:**

Please produce, for the request above, all materials, including but not limited to PowerPoint presentations, syllabus, medical journal articles, summaries, agendas, etc., provided to or shown as part of the LILLY-sponsored program.

**REQUEST FOR PRODUCTION NO. 96:**

Please produce all records in YOUR possession related to Plaintiff. Please note that this request is in no way limited to medical or psychiatric records, but includes any DOCUMENTS obtained from a third-party by LILLY about the Plaintiff.

**REQUEST FOR PRODUCTION NO. 97:**

Please produce all DOCUMENTS reflecting any correspondence created in collecting the

records described in the above request.

**VII. OTHER REQUESTS**

**REQUEST FOR PRODUCTION NO. 98:**

Please produce all DOCUMENTS identified in YOUR answers to all of Plaintiff's Interrogatories.

**REQUEST FOR PRODUCTION NO. 99:**

Please produce all DOCUMENTS from which YOU obtained answers in responding to all of Plaintiff's Interrogatories.

**REQUEST FOR PRODUCTION NO. 100:**

Please produce the custodial file, including but not limited to employment agreements, termination agreements, performance reviews, self-reviews, W-2s, and bonus amounts, for each individual presented by LILLY as a person most knowledgeable under Federal Rule of Civil Procedure 30(b)(6).

**REQUEST FOR PRODUCTION NO. 101:**

Please produce all electronic mail ("email") for the individuals presented by LILLY as a person most knowledgeable under Federal Rule of Civil Procedure 30(b)(6), whether internal or external and whether on LILLY's current computer operating system, on individual employees' laptop computers, or archive systems, which contain at least one of the following terms:

**Cy!, dulo!, Aricclaim, Xeristar, Yentreve, Duzela, Dulane, Cymgen, Prozac, Fluox!, Paxil, Parox!, Zolofit, Sertra!, Celexa, Citalop!, Lexapro, Escitalop!, Effexor, venlafa!, Pristiq, desvenlafax!, milnacipr!, levomilnacipr!, SSRI!, SNRI!, or anti!,**

*and* at least one of the following terms:

**DEAE!, discon!, withd!, taper!, cold w/1turkey, addict!, habit!, paresth!, zap!, electric w/4**

shock, dizz!, Rosenbaum, Schatzberg, Glenmullen, half-life, “missed dose,” downregu!,  
“greater than or equal to,” Perahia, enteric, or time-release.

**REQUEST FOR PRODUCTION NO. 102:**

Please produce all DOCUMENTS in LILLY’s possession, custody or control concerning any governmental investigations of LILLY in relation to CYMBALTA and, in any way, with WITHDRAWAL.

**REQUEST FOR PRODUCTION NO. 103:**

With respect to Lilly’s Patient Assistance and/or Lilly Cares Program for CYMBALTA, please produce all documents regarding Lilly’s decision to establish the program; its structure and budget; its criteria for deciding which patients qualify for the program; and any complaints, questions, or comments received from participants, physicians, or pharmacies.

**REQUEST FOR PRODUCTION NO. 104:**

Please produce all DOCUMENTS pertaining to Lilly’s provision of CYMBALTA to Plaintiff, if applicable, as part of Lilly’s Patient Assistance and/or Lilly Cares program.

**REQUEST FOR PRODUCTION NO. 105:**

Please produce all Corporate Integrity Agreements LILLY has entered into with any government for any reason.

Dated: February 4, 2015

Respectfully submitted,  
**MILLER LEGAL, LLC**

/s/ Brielle M. Hunt  
Brielle M. Hunt  
Miller Legal, LLC  
175 South Pantops Drive, Ste. 301  
Charlottesville, Virginia 22911  
Tel: (434) 529-6909  
Fax: (800) 768-9542  
Email: [bhunt@millerlegalllc.com](mailto:bhunt@millerlegalllc.com)

-and-

**BAUM HEDLUND ARISTEI & GOLDMAN,  
P.C.**

/s/ R. Brent Wisner

Brent Wisner, Esq. (*pro hac vice*)

12100 Wilshire Blvd., Suite 950

Los Angeles, CA 90025

(310) 207-3233

(310) 207-4204 (fax)

Email: [rbwisner@baumgedlundlaw.com](mailto:rbwisner@baumgedlundlaw.com)

**CERTIFICATE OF SERVICE**

I hereby certify that on this 4<sup>th</sup> day of February, 2015, a true and correct copy of the foregoing **PLAINTIFF'S FIRST SET OF REQUESTS FOR PRODUCTION OF DOCUMENTS** was served via Electronic Mail, upon the following:

Jeffrey Todd Bozman  
Brett C. Reynolds (pro hac vice)  
Michael X. Imbroscio (pro hac vice)  
Phyllis A. Jones (pro hac vice)  
**COVINGTON & BURLING LLP**  
One City Center  
850 Tenth Street, NW  
Washington, DC 20001  
Email: [jbozman@cov.com](mailto:jbozman@cov.com)  
Email: [breynolds@cov.com](mailto:breynolds@cov.com)  
Email: [mimbrosio@cov.com](mailto:mimbrosio@cov.com)  
Email: [pajones@cov.com](mailto:pajones@cov.com)

*Attorneys for Eli Lilly and Company*

/s/

\_\_\_\_\_  
Samantha Jison

## Exhibit 1-B



**UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF VIRGINIA  
ALEXANDRIA DIVISION**

JANINE ALI

Plaintiff,

v.

ELI LILLY AND COMPANY, an Indiana  
corporation,

Defendant.

CASE NO.: 1:14-CV-01615-GBL-TRJ

**DEFENDANT’S OBJECTIONS TO PLAINTIFF’S FIRST SET OF REQUESTS FOR  
PRODUCTION OF DOCUMENTS**

Defendant Eli Lilly and Company (“Defendant” or “Lilly”) hereby submits its objections to Plaintiff’s First Set of Requests for Production, as follows:

**GENERAL STATEMENTS AND OBJECTIONS**

Lilly objects to these Requests as overly broad, unduly burdensome, and not in proportion to the needs of the case, particularly to the extent they seek documents or information that are already in Plaintiff’s possession, custody, or control. Lilly has produced more than 2.5 million documents in *Hexum v. Eli Lilly & Co.*, Case No. 2:12-cv-2701-SVW (MAN) (C.D. Cal) and *Herrera v. Eli Lilly & Co.*, Case No. 2:12-cv-2702-SVW (MAN) (C.D. Cal.) (the “*Hexum/Herrera* actions”), pending actions concerning discontinuation-emergent adverse events allegedly arising from treatment with Cymbalta, the same subject matter as the allegations in this litigation. Plaintiff has access to those productions, yet Plaintiff has propounded these 105 Requests, broadly seeking documents that are contained in Lilly’s productions, are available in the public domain, or are of marginal relevance in this action. The purpose of the parties’

agreement to grant Plaintiff access to Lilly's productions in the *Hexum/Herrera* actions was to obviate the need for such extensive, burdensome discovery in this matter.

### **OBJECTIONS TO DEFINITIONS AND INSTRUCTIONS**

1. Lilly objects to the definitions of the terms "ELI LILLY", "LILLY", "YOU", and "YOUR" to the extent that they seek to extend these definitions to persons or entities other than the named Defendant in this litigation, Eli Lilly and Company, and purport to call for information or documents that are not in the possession, custody, or control of Eli Lilly and Company. For purposes of its objections and responses, Lilly will define "ELI LILLY", "LILLY", "YOU", and "YOUR" to mean Eli Lilly and Company. Lilly will limit its responses to information and documents that are in the possession, custody, or control of Eli Lilly and Company.

2. Lilly objects to the definition of "DOCUMENT" to the extent that it imposes obligations on Lilly beyond those in the Federal Rules of Civil Procedure.

3. Lilly objects to Instruction Number 1 to the extent that it does not comport with the Federal Rules of Civil Procedure and the Local Civil Rules of the Eastern District of Virginia.

4. Lilly objects to Instruction Number 7 to the extent that it imposes burdens on Lilly beyond its obligations under the Federal Rules of Civil Procedure.

5. Lilly objects to Instruction Number 11 to the extent that its use of the term "Electronically stored information" imposes burdens on Lilly beyond its obligations under the Federal Rules of Civil Procedure. Lilly also objects to the extent that this Instruction calls for the search and production of information from, including but not limited to, "hard disks, floppy disks, optical disks, flash memory devices, and magnetic tape, whether fixed, portable, or

removable.” A search of such sources and production of such data is overly broad, unduly burdensome, and not calculated to lead to the discovery of admissible evidence.

6. Lilly objects to Instruction Number 13 to the extent that it imposes burdens on Lilly beyond its obligations under the Federal Rules of Civil Procedure.

### **SPECIFIC OBJECTIONS TO REQUESTS FOR PRODUCTION**

#### **I. FDA DOCUMENTS**

##### **REQUEST FOR PRODUCTION NO. 1:**

Please produce the Electronic Common Technical Document (eCTD) or equivalent electronic submission for all CYMBALTA indications, whether that indication was approved or denied, including but not limited to: Major Depressive Disorder (MDD), Generalized Anxiety Disorder (GAD), Neuropathic Pain from Diabetes, Chronic Pain, Chronic Musculoskeletal Pain, Fibromyalgia, MDD Maintenance, GAD Maintenance, and Stress Urinary Incontinence (SUI).

##### **OBJECTIONS TO REQUEST FOR PRODUCTION NO. 1:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request and its use of “Electronic Common Technical Document (eCTD)” as vague and ambiguous. Lilly construes “Electronic Common Technical Document (eCTD)” to mean Lilly’s Investigational New Drug (“IND”) submission and New Drug Application (“NDA”) submissions to FDA for Cymbalta indications. Subject to the foregoing objections, Lilly will direct Plaintiff within its prior productions to documents from its IND/NDA submissions to FDA for Cymbalta.

**REQUEST FOR PRODUCTION NO. 2:**

Please produce the Summary Basis of Approval for CYMBALTA for the following indications: Major Depressive Disorder (MDD), Generalized Anxiety Disorder (GAD), Neuropathic Pain from Diabetes, Chronic Pain, Chronic Musculoskeletal Pain, Fibromyalgia, MDD Maintenance, and GAD Maintenance.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 2:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request to the extent it seeks publicly available information given that the Summary Basis of Approval is an FDA created document available on FDA's website.

**REQUEST FOR PRODUCTION NO. 3:**

Please produce all Periodic Safety Updates regarding CYMBALTA for the following indications: Major Depressive Disorder (MDD), Generalized Anxiety Disorder (GAD), Neuropathic Pain from Diabetes, Chronic Pain, Chronic Musculoskeletal Pain, Fibromyalgia, MDD Maintenance, and GAD Maintenance.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 3:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Subject to the foregoing objections, Lilly will direct Plaintiff within its prior production to its Periodic Safety Update Reports.

**REQUEST FOR PRODUCTION NO. 4:**

Please produce all Annual Safety Updates regarding CYMBALTA for the following indications: Major Depressive Disorder (MDD), Generalized Anxiety Disorder (GAD), Neuropathic Pain from Diabetes, Chronic Pain, Chronic Musculoskeletal Pain, Fibromyalgia, MDD Maintenance, and GAD Maintenance.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 4:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request and its use of “Annual Safety Updates” as vague and ambiguous. Lilly construes “Annual Safety Updates” to mean Periodic Safety Update Reports and objects to this request as duplicative of Request No. 3.

**REQUEST FOR PRODUCTION NO. 5:**

Please produce the electronic Investigational New Drug (“IND”) file for CYMBALTA.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 5:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Moreover, Lilly objects to this request as duplicative of Request No. 1.

**REQUEST FOR PRODUCTION NO. 6:**

Please produce all warning letters sent to YOU from the FDA regarding CYMBALTA.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 6:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which

Plaintiff has access. Lilly also objects to this Request and its use of “warning letters” as vague and ambiguous. Moreover, Lilly objects to this Request as it is not limited to documents relating to any alleged discontinuation-emergent adverse events potentially arising from Cymbalta treatment and therefore seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence. Subject to the foregoing objections, Lilly will direct Plaintiff within its prior production to letters it received from FDA’s Division of Drug Marketing, Advertising, and Communications (“DDMAC”) regarding Cymbalta.

**REQUEST FOR PRODUCTION NO. 7:**

Please produce YOUR responses to all warning letters sent to YOU from the FDA regarding CYMBALTA.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 7:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request and its use of “warning letters” as vague and ambiguous. Moreover, Lilly objects to this Request as it is not limited to documents relating to any alleged discontinuation-emergent adverse events potentially arising from Cymbalta treatment and therefore seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence. Subject to the foregoing objections, Lilly will direct Plaintiff within its prior production to its responses to letters it received from FDA’s Division of Drug Marketing, Advertising, and Communications (“DDMAC”) regarding Cymbalta.

**REQUEST FOR PRODUCTION NO. 8:**

Please produce the transcript of any FDA Advisory Committee meetings regarding CYMBALTA for any indication.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 8:**

Lilly objects to this Request to the extent it seeks publicly available information.

**REQUEST FOR PRODUCTION NO. 9:**

Please produce any DOCUMENTS submitted to the FDA as part of any Advisory Committee meeting related to CYMBALTA.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 9:**

Lilly objects to this Request to the extent it seeks publicly available information.

**REQUEST FOR PRODUCTION NO. 10:**

Please produce any and all Form 483 and/or Warning Letters that YOU received from the FDA related to CYMBALTA.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 10:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request and its use of “Warning Letters” as vague and ambiguous. Lilly further objects to this Request as it is not limited to documents relating to any alleged discontinuation-emergent adverse events potentially arising from Cymbalta treatment and therefore seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence. Moreover, Lilly objects to this request as duplicative of Request No. 6.

**REQUEST FOR PRODUCTION NO. 11:**

Please produce YOUR responses to all Form 483 and/or Warning Letters that YOU received from the FDA related to CYMBALTA.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 11:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request and its use of “Warning Letters” as vague and ambiguous. Lilly further objects to this Request as it is not limited to documents relating to any alleged discontinuation-emergent adverse events potentially arising from Cymbalta treatment and therefore seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence. Moreover, Lilly objects to this request as duplicative of Request No. 7.

**REQUEST FOR PRODUCTION NO. 12:**

Please produce all DOCUMENTS reflecting any settlements, agreements, resolutions, fines, sanctions and/or additional regulatory actions that arose as a result of the Form 483 and/or Warning Letters that YOU received from the FDA related to CYMBALTA.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 12:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request and its use of “Warning Letters” as vague and ambiguous. Lilly further objects Lilly also objects to this Request as it is not limited to documents relating to any alleged discontinuation-emergent adverse events potentially arising from Cymbalta treatment and therefore seeks information that is neither relevant nor likely to



lead to the discovery of admissible evidence. Moreover, Lilly objects to this request as duplicative of Requests Nos. 6 and 7.

**REQUEST FOR PRODUCTION NO. 13:**

Please produce all DOCUMENTS related to any COMMUNICATIONS with the FDA about CYMBALTA containing any of the following terms (or any derivative term): DEAE, withdrawal, discontinuation or discontinuing, dependence, habit-forming, addiction, quitting, tapering, brain zaps, electric shock, down regulation, half-life, missed dose, “greater than or equal to,” Perahia, Rosenbaum, or Schatzberg.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 13:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Those productions include communications between Lilly and FDA about Cymbalta and discontinuation-emergent adverse events, as well as email files from nine Lilly employees who had significant involvement in or responsibility for Cymbalta that were responsive to certain Cymbalta-related and discontinuation-related search terms. To the extent this Request seeks documents beyond those described above, the burden of complying with the Request outweighs Plaintiff’s need for documents of this scope. Lilly also objects to this Request to the extent it is not limited to documents relating to any alleged discontinuation-emergent adverse events potentially arising from Cymbalta treatment and therefore seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence.

**REQUEST FOR PRODUCTION NO. 14:**

Please produce all DOCUMENTS related to any COMMUNICATIONS with the FDA about Prozac or fluoxetine containing any of the following terms (or any derivative term): DEAE, withdrawal, discontinuation or discontinuing, dependence, habit-forming, addiction, quitting, tapering, brain zaps, electric shock, down regulation, half-life, missed dose, “greater than or equal to,” Perahia, Rosenbaum, or Schatzberg.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 14:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request as it is not to limited documents relating to Cymbalta and therefore seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence. The Complaint does not allege that Plaintiff was treated with Prozac, and as such, documents relating to Prozac or fluoxetine are irrelevant in this matter. Subject to the foregoing objections, Lilly will direct Plaintiff within its prior production to documents relating to Prozac and discontinuation symptoms.

**REQUEST FOR PRODUCTION NO. 15:**

Please produce all DOCUMENTS related to any COMMUNICATIONS with the FDA about Zyprexa or olanzapine containing any of the following terms (or any derivative term): DEAE, withdrawal, discontinuation or discontinuing, dependence, habit-forming, addiction, quitting, tapering, brain zaps, electric shock, down regulation, half-life, missed dose, “greater than or equal to,” Perahia, Rosenbaum, or Schatzberg.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 15:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope. Lilly also objects to this Request as it is not limited to documents relating to Cymbalta and therefore seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence. The Complaint does not allege that Plaintiff was treated with Zyprexa, an antipsychotic that is not in the same class of medications as Cymbalta, and as such, documents relating to Zyprexa or olanzapine are irrelevant in this matter.

**REQUEST FOR PRODUCTION NO. 16:**

Please produce all DOCUMENTS reflecting COMMUNICATIONS with the FDA about the section of the US LABEL titled “Discontinuation of Treatment with Cymbalta.”

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 16:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly. Plaintiff has access to Lilly’s Investigational New Drug application and New Drug Application productions in the *Hexum/Herrera* actions, which contain communications between Lilly and FDA about Cymbalta’s United States Package Insert (“U.S. label”), including drafts and mark-ups of the U.S. label.

**REQUEST FOR PRODUCTION NO. 17:**

Please produce all DOCUMENTS reflecting COMMUNICATIONS with the FDA about the sections of the US LABEL titled “Dosage and Administration” or “Medication Administration” or “Information for Patients” (depending on year).

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 17:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly. Plaintiff has access to Lilly's Investigational New Drug application and New Drug Application productions in the *Hexum/Herrera* actions, which contain communications between Lilly and FDA about Cymbalta's U.S. label, including drafts and mark-ups of the U.S. label.

**REQUEST FOR PRODUCTION NO. 18:**

Please produce all DOCUMENTS that reflect COMMUNICATIONS between LILLY and the FDA concerning LILLY's Medical Information Letters, or similar letters, concerning the potential risk of withdrawal or discontinuation from CYMBALTA.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 18:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request and its use of "similar letters" as vague and ambiguous. Medical information letters do not undergo a FDA submission and review process. Subject to the foregoing objections, Lilly with direct Plaintiff within its prior productions to its medical information letters concerning Cymbalta and discontinuation-emergent adverse events.

**REQUEST FOR PRODUCTION NO. 19:**

Please produce all COMMUNICATIONS between YOU and the FDA concerning the half-life of CYMBALTA.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 19:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly. Plaintiff has access to Lilly's Investigational New Drug application and New Drug Application productions in the *Hexum/Herrera* actions, which contain communications between Lilly and FDA about Cymbalta's U.S. label, which includes information about Cymbalta's half-life.

**REQUEST FOR PRODUCTION NO. 20:**

Please produce all COMMUNICATIONS between YOU and the FDA concerning the enteric coating of CYMBALTA.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 20:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly. Plaintiff has access to Lilly's Investigational New Drug application and New Drug Application productions in the *Hexum/Herrera* actions, which contain communications between Lilly and FDA about Cymbalta's U.S. label, which includes information and warnings about Cymbalta's enteric coating.

**REQUEST FOR PRODUCTION NO. 21:**

Please produce a copy of each FDA-approved version of the package insert for CYMBALTA used by LILLY since it began marketing CYMBALTA in the United States.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 21:**

Lilly objects to this Request as overly broad and unduly burdensome to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access.

**REQUEST FOR PRODUCTION NO. 22:**

Please produce a copy of each version of the LABEL for CYMBALTA in each foreign country wherein CYMBALTA was approved for marketing in that country.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 22:**

Lilly objects to this Request as overly broad and unduly burdensome to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access or documents that are publicly available. The Complaint alleged that Plaintiff was treated with Cymbalta in the United States based on labeling information that was approved by the FDA, and to the extent that this Request seeks labeling information approved by foreign regulatory bodies outside the United States, these documents are not relevant nor likely to lead to the discovery of admissible evidence.

**REQUEST FOR PRODUCTION NO. 23:**

Please produce the electronic Adverse Event Reporting database for CYMBALTA.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 23:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request as it is not limited to documents relating to any alleged discontinuation-emergent adverse events potentially arising from Cymbalta treatment and therefore seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence. Lilly further objects to this Request to this extent that it seeks personal health information protected under HIPAA and other privacy laws. Moreover, Lilly's database for adverse events is accessible only using specialized software, and Lilly objects to this Request as unduly burdensome to the extent it seeks contents of this database in its native

format. Subject to the foregoing objections, Lilly will direct Plaintiff within its prior productions to Cymbalta adverse event data that have been produced in Excel format.

## **II. INTERNAL COMMUNICATIONS ABOUT CYMBALTA**

### **REQUEST FOR PRODUCTION NO. 24:**

Please produce all DOCUMENTS reflecting LILLY's internal COMMUNICATIONS and/or deliberations concerning the section of the US CYMBALTA LABEL titled "Discontinuation of Treatment with Cymbalta," including not limited to all emails, memorandums, drafts, comments, edits, redlines, or discussions about those edits of those sections of the US CYMBALTA LABEL.

### **OBJECTIONS TO REQUEST FOR PRODUCTION NO. 24:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request and its use of "deliberations" and "discussions" as vague and ambiguous. Lilly has searched the email files of nine Lilly employees who had significant involvement in or responsibility for Cymbalta and produced documents that were responsive to certain Cymbalta-related and discontinuation-related search terms. Plaintiff has access to those documents. To the extent that this Request for "all DOCUMENTS" requires Lilly to expand its efforts to a company-wide search, the burden of complying with the Request outweighs Plaintiff's need for documents of this scope.

### **REQUEST FOR PRODUCTION NO. 25:**

Please produce all DOCUMENTS reflecting LILLY's internal COMMUNICATIONS and/or deliberations concerning the section of the US CYMBALTA LABEL titled "Dosage and

Administration” or “Medication Administration” or “Information for Patients” (depending on year), including not limited to all emails, memorandums, drafts, comments, edits, redlines, or discussions about those edits of the that section of the US CYMBALTA LABEL.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 25:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request and its use of “deliberations” and “discussions” as vague and ambiguous. Lilly has searched the email files of nine Lilly employees who had significant involvement in or responsibility for Cymbalta and produced documents that were responsive to certain Cymbalta-related and discontinuation-related search terms. Plaintiff has access to those documents. To the extent that this Request for “all DOCUMENTS” requires Lilly to expand its efforts to a company-wide search, the burden of complying with the Request outweighs Plaintiff’s need for documents of this scope.

**REQUEST FOR PRODUCTION NO. 26:**

Please produce all DOCUMENTS reflecting LILLY’s internal COMMUNICATIONS and/or deliberations concerning the following sentences in the US CYMBALTA LABEL as it was approved in 2004, including but not limited to all emails, memorandums, drafts, comments, edits, redlines, or discussions about those edits: “Duloxetine should be swallowed whole and should not be chewed or crushed, nor should the contents be sprinkled on food or mixed with liquids. All of these might affect the enteric coating.”

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 26:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which



Plaintiff has access. Lilly also objects to this Request and its use of “deliberations” and “discussions” as vague and ambiguous. Lilly has searched the email files of nine Lilly employees who had significant involvement in or responsibility for Cymbalta and produced documents that were responsive to certain Cymbalta-related and discontinuation-related search terms. Plaintiff has access to those documents. To the extent that this Request for “all DOCUMENTS” requires Lilly to expand its efforts to a company-wide search, the burden of complying with the Request outweighs Plaintiff’s need for documents of this scope.

**REQUEST FOR PRODUCTION NO. 27:**

Please produce all DOCUMENTS that reflect LILLY’s reason for changing the US LABEL concerning “Discontinuation of Treatment with Cymbalta” in 2008 from “the following symptoms occurred at a rate greater than or equal to 2%” to “the following symptoms occurred at a rate greater than or equal to 1%.”

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 27:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly has searched the email files of nine Lilly employees who had significant involvement in or responsibility for Cymbalta and produced documents that were responsive to certain Cymbalta-related and discontinuation-related search terms. Lilly’s prior productions also include communications between Lilly and FDA about changes to the language in Cymbalta’s U.S. label. Plaintiff has access to those documents. To the extent that this Request for “all DOCUMENTS” requires Lilly to expand its efforts to a company-wide search, the burden of complying with the Request outweighs Plaintiff’s need for documents of this scope.

**REQUEST FOR PRODUCTION NO. 28:**

Please produce all DOCUMENTS that reflect LILLY's reason for adding to the 2009 US CYMBALTA LABEL "or tapered" in the context of "Following abrupt ... discontinuation ..." in the section titled "Discontinuation of Treatment with Cymbalta."

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 28:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly has searched the email files of nine Lilly employees who had significant involvement in or responsibility for Cymbalta and produced documents that were responsive to certain Cymbalta-related and discontinuation-related search terms. Lilly's prior productions also include communications between Lilly and FDA about changes to the language in Cymbalta's U.S. label. Plaintiff has access to those documents. To the extent that this Request for "all DOCUMENTS" requires Lilly to expand its efforts to a company-wide search, the burden of complying with the Request outweighs Plaintiff's need for documents of this scope.

**REQUEST FOR PRODUCTION NO. 29:**

Please produce all DOCUMENTS that reflect LILLY's reason for changing the US CYMBALTA LABEL in 2012 from "the following symptoms occurred at a rate greater than or equal to 1%" to "at 1% or greater" in the section titled "Discontinuation of Treatment with Cymbalta."

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 29:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which

Plaintiff has access. Lilly has searched the email files of nine Lilly employees who had significant involvement in or responsibility for Cymbalta and produced documents that were responsive to certain Cymbalta-related and discontinuation-related search terms. Lilly's prior productions also include communications between Lilly and FDA about changes to the language in Cymbalta's U.S. label. Plaintiff has access to those documents. To the extent that this Request for "all DOCUMENTS" requires Lilly to expand its efforts to a company-wide search, the burden of complying with the Request outweighs Plaintiff's need for documents of this scope.

**REQUEST FOR PRODUCTION NO. 30:**

Please produce all DOCUMENTS that reflect LILLY's reason for creating CYMBALTA as capsules containing enteric-coated pellets of duloxetine hydrochloride.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 30:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request to the extent that it seeks documents concerning Cymbalta's design or manufacture that are not limited to documents about any alleged discontinuation-emergent adverse events potentially arising from Cymbalta treatment and therefore seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence.

**REQUEST FOR PRODUCTION NO. 31:**

Please produce all DOCUMENTS reflecting LILLY's internal COMMUNICATIONS and/or deliberations concerning the design of CYMBALTA as enteric-coated pellets contained within a capsule.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 31:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request and its use of "deliberations" as vague and ambiguous. Lilly further objects to this Request to the extent that it seeks documents concerning Cymbalta's design or manufacture that are not limited to documents about any alleged discontinuation-emergent adverse events potentially arising from Cymbalta treatment and therefore seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence. Moreover, Lilly objects to this request as duplicative of Request No. 30.

**REQUEST FOR PRODUCTION NO. 32:**

Please produce all DOCUMENTS reflecting LILLY's internal COMMUNICATIONS and/or deliberations concerning the development of a dosage of CYMBALTA below 20mg.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 32:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request and its use of "deliberations" as vague and ambiguous. Lilly further objects to this Request to the extent that it seeks documents concerning development of Cymbalta's dosages that are not limited to documents about any alleged discontinuation-emergent adverse events potentially arising from Cymbalta treatment and

therefore seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence.

**REQUEST FOR PRODUCTION NO. 33:**

Please produce all DOCUMENTS reflecting LILLY's internal COMMUNICATIONS and/or deliberations concerning the development of CYMBALTA as a scored tablet.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 33:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request and its use of "deliberations" as vague and ambiguous. Lilly further objects to this Request to the extent that it seeks documents concerning Cymbalta's design or manufacture that are not limited to documents about any alleged discontinuation-emergent adverse events potentially arising from Cymbalta treatment and therefore seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence. Moreover, Lilly objects to this request as duplicative of Request Nos. 30 and 31.

**REQUEST FOR PRODUCTION NO. 34:**

Please produce all memoranda, presentations, and/or reports, whether prepared internally or provided to LILLY by a third-party, that discuss, in any way, CYMBALTA and WITHDRAWAL.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 34:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which

Plaintiff has access. Lilly has searched the email files of nine Lilly employees who had significant involvement in or responsibility for Cymbalta and produced documents that were responsive to certain Cymbalta-related and discontinuation-related search terms. Lilly's prior productions also include communications between Lilly and FDA including reports that discuss discontinuation-emergent adverse events. Plaintiff has access to those documents. To the extent that this Request for "all DOCUMENTS" requires Lilly to expand its efforts to a company-wide search, the burden of complying with the Request outweighs Plaintiff's need for documents of this scope.

**REQUEST FOR PRODUCTION NO. 35:**

Please produce all electronic mail ("email") for the individuals identified in Interrogatory Nos. 1 & 3, whether internal or external and whether on LILLY's current computer operating system, on individual employees' laptop computers, or archive systems, which contain at least one of the following terms:

**Cy!, dulo!, Ariclain, Xeristar, Yentreve, Duzela, Dulane, Cymgen, Prozac, Fluox!, Paxil, Parox!, Zolof, Sertra!, Celexa, Citalop!, Lexapro, Escitalop!, Effexor, venlafa!, Pristiq, desvenlafax!, milnacipr!, levomilnacipr!, SSRI!, SNRI!, or anti!,**

*and* at least one of the following terms:

**DEAE!, discon!, withd!, taper!, cold w/1turkey, addict!, habit!, paresth!, zap!, electric w/4 shock, dizz!, Rosenbaum, Schatzberg, Glenmullen, half-life, "missed dose," downregu!, "greater than or equal to," Perahia, enteric, pellets, "delayed release."**

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 35:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which

Plaintiff has access. Lilly also objects to this Request as not limited to documents relating to Cymbalta or any alleged discontinuation-emergent adverse events potentially arising from Cymbalta treatment. Lilly further objects to terms such as “anti!”, “addict!”, “habit!”, “greater than or equal to”, or “delayed release” as overly broad and far beyond the scope of the allegations of the Complaint. Lilly has searched the email files of nine Lilly employees who had significant involvement in or responsibility for Cymbalta and produced documents that were responsive to certain Cymbalta-related and discontinuation-related search terms, including many of the terms contained in this Request. Plaintiff has access to those documents. To the extent that this Request seeks documents beyond those described above, the burden of complying with the Request outweighs Plaintiff’s need for documents of this scope.

**REQUEST FOR PRODUCTION NO. 36:**

Please produce all DOCUMENTS that reflect LILLY’s internal COMMUNICATIONS and/or deliberations concerning any and all letters used by LILLY to respond to inquiries regarding CYMBALTA and DEAEs, discontinuation, withdrawal, dependence, or addiction.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 36:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request and its use of “deliberations” as vague and ambiguous. Lilly has searched the email files of nine Lilly employees who had significant involvement in or responsibility for Cymbalta and produced documents that were responsive to certain Cymbalta-related and discontinuation-related search terms. Lilly has also produced its medical information letters used to respond to inquiries from medical professionals about Cymbalta and discontinuation. Plaintiff has access to those documents. To the extent that this

Request for “all DOCUMENTS” requires Lilly to expand its efforts to a company-wide search, the burden of complying with the Request outweighs Plaintiff’s need for documents of this scope.

**REQUEST FOR PRODUCTION NO. 37:**

Please produce all DOCUMENTS that reflect LILLY’s internal COMMUNICATIONS and/or deliberations concerning any of LILLY’s Medical Information Letters, or similar letters, concerning the potential risk of withdrawal or discontinuation from CYMBALTA.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 37:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request and its use of “deliberations” and “similar letters” as vague and ambiguous. Lilly has searched the email files of nine Lilly employees who had significant involvement in or responsibility for Cymbalta and produced documents that were responsive to certain Cymbalta-related and discontinuation-related search terms. Lilly has also produced its medical information letters used to respond to inquiries from medical professionals about Cymbalta and discontinuation. Plaintiff has access to those documents. To the extent that this Request for “all DOCUMENTS” requires Lilly to expand its efforts to a company-wide search, the burden of complying with the Request outweighs Plaintiff’s need for documents of this scope. Moreover, Lilly objects to this request as duplicative of Request No. 36.

**REQUEST FOR PRODUCTION NO. 38:**

Please produce all minutes of meetings of any LILLY committee, working group, department, board, etc. where CYMBALTA and WITHDRAWAL were discussed.



**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 38:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly has searched the email files of nine Lilly employees who had significant involvement in or responsibility for Cymbalta and produced documents that were responsive to certain Cymbalta-related and discontinuation-related search terms, including any responsive meeting minutes. Plaintiff has access to those documents. To the extent that this Request for “all minutes of meetings” requires Lilly to expand its efforts to a company-wide search, the burden of complying with the Request outweighs Plaintiff’s need for documents of this scope.

**REQUEST FOR PRODUCTION NO. 39:**

Please produce all DOCUMENTS that reflect LILLY’s internal COMMUNICATIONS and/or deliberations concerning why the rate of WITHDRAWAL reflected in the PERAHIA article was not included in the US LABEL.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 39:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request and its use of “deliberations” as vague and ambiguous. Lilly has searched the email files of nine Lilly employees who had significant involvement in or responsibility for Cymbalta, including Dr. David Perahia, and produced documents that were responsive to certain Cymbalta-related and discontinuation-related search terms. Plaintiff has access to those documents. To the extent that this Request for “all

DOCUMENTS” requires Lilly to expand its efforts to a company-wide search, the burden of complying with the Request outweighs Plaintiff’s need for documents of this scope.

**REQUEST FOR PRODUCTION NO. 40:**

Please produce all DOCUMENTS that reflect LILLY’s internal COMMUNICATIONS and/or deliberations concerning why the rate of WITHDRAWAL reflected in the PERAHIA article was included in the European LABEL.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 40:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request and its use of “deliberations” as vague and ambiguous. Lilly has searched the email files of nine Lilly employees who had significant involvement in or responsibility for Cymbalta, including Dr. David Perahia, and produced documents that were responsive to certain Cymbalta-related and discontinuation-related search terms. Plaintiff has access to those documents. To the extent that this Request for “all DOCUMENTS” requires Lilly to expand its efforts to a company-wide search, the burden of complying with the Request outweighs Plaintiff’s need for documents of this scope. Subject to the foregoing, Lilly will direct Plaintiff within its prior productions to documents concerning the European Medicines Agency’s request for the inclusion in the European labels for SSRIs and SNRIs of the aggregate rate of discontinuation-emergent adverse events from clinical trials.

**REQUEST FOR PRODUCTION NO. 41:**

Please produce all DOCUMENTS that reflect LILLY’s internal COMMUNICATIONS concerning discontinuation or withdrawal symptoms upon discontinuation of Effexor, including

but not limited to any discussion concerning the language contained in the US Effexor LABEL concerning WITHDRAWAL.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 41:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope. Lilly also objects to this Request as it is not limited to documents relating to Cymbalta and therefore seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence. A third party, not Lilly, manufactures Effexor, and the Complaint does not allege that Plaintiff was treated with Effexor. As such, documents relating to Effexor or venlafaxine are irrelevant in this matter and not likely to lead to the discovery of admissible evidence.

**III. COMMUNICATIONS WITH MEDICAL PROFESSIONALS**  
**REQUEST FOR PRODUCTION NO. 42:**

Please produce any “Dear Healthcare Professional” or similar letters to doctors, pharmacies or other groups, organizations about CYMBALTA.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 42:**

Lilly objects to this Request as overly broad and unduly burdensome to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request and its use of “similar letters”, “groups”, and “organizations” as vague and ambiguous. Subject to the foregoing objections, Lilly will direct Plaintiff within its prior productions to any Dear Healthcare Professional letters.

**REQUEST FOR PRODUCTION NO. 43:**

Please produce all DOCUMENTS that contain a record or description of COMMUNICATIONS to LILLY from MEDICAL PROFESSIONALS or the public, including but not limited to call logs, inquiring about CYMBALTA that mention DEAEs, withdrawal, discontinuation or discontinuing, dependence, habit-forming, addiction, quitting, tapering, brain zaps, electric shock, down regulation, half-life (or any related or derivative terms).

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 43:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Those productions include records of inquiries from medical professionals concerning Cymbalta and discontinuation.

**REQUEST FOR PRODUCTION NO. 44:**

Please produce any and all letters used by LILLY to respond to inquiries regarding CYMBALTA and DEAEs, discontinuation, withdrawal, dependence, or addiction.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 44:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Subject to the foregoing objections, Lilly will direct Plaintiff within its prior productions to its medical information letters concerning Cymbalta and discontinuation.

**REQUEST FOR PRODUCTION NO. 45:**

Please produce a copy of each and every version of LILLY's "Medical Information Letter" or similar letters to doctors, pharmacies or other groups, organizations or entities discussing the potential risk of withdrawal or discontinuation from CYMBALTA.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 45:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request and its use of "similar letters", "groups", and "organizations" as vague and ambiguous. Lilly further objects to this Request as duplicative of Request No. 44.

**REQUEST FOR PRODUCTION NO. 46:**

Please produce all DOCUMENTS that identify MEDICAL PROFESSIONALS to whom LILLY sent a Medical Information Letter concerning the potential risk of withdrawal or discontinuation from CYMBALTA (e.g., an Excel spreadsheet or Access spreadsheet).

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 46:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and subject matter. Lilly also objects to this Request as it is not limited to information about medical professionals who treated Plaintiff and therefore seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence. Only certain physicians treated Plaintiff, and documents concerning other medical professionals to whom Lilly sent medical information letters are irrelevant to this matter and not likely to lead to the discovery of admissible evidence.

**REQUEST FOR PRODUCTION NO. 47:**

Please produce any and all DOCUMENTS that reflect each inquiry from a MEDICAL PROFESSIONAL concerning Cymbalta and withdrawal or discontinuation, including but not limited to written letters, telephone calls, online requests, sales representative relay.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 47:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Those productions include records of inquiries from medical professionals concerning Cymbalta and discontinuation. Lilly also objects to this Request as duplicative of Request No. 43.

**IV. MEDICAL LITERATURE AND CONTINUING MEDICAL EDUCATION**  
**REQUEST FOR PRODUCTION NO. 48:**

Please produce all publication plans for CYMBALTA, whether prepared internally or by a third-party.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 48:**

Lilly objects to this Request as overly broad as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request as it is not limited to documents relating to alleged discontinuation-emergent adverse events potentially arising from Cymbalta treatment and therefore seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence. Plaintiff is aware of the publications involving Cymbalta that relate to the discontinuation symptoms that are the focus of this lawsuit.

**REQUEST FOR PRODUCTION NO. 49:**

Please produce all DOCUMENTS reflecting LILLY's involvement in the drafting, editing, and publication the PERAHIA ARTICLE, including but not limited to all email communications, article drafts, and publication plans relating to the PERAHIA ARTICLE.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 49:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Those productions include a copy of the PERAHIA ARTICLE and documents from Dr. David Perahia's email files that were responsive to certain Cymbalta-related and discontinuation-related search terms. To the extent that this Request for "all DOCUMENTS" requires Lilly to expand its efforts to a company-wide search, the burden of complying with the Request outweighs Plaintiff's need for documents of this scope. Lilly also objects to the Request to the extent it is duplicative of Request No. 48.

**REQUEST FOR PRODUCTION NO. 50:**

Please produce the study protocol and final study reports for each of the CYMBALTA trials discussed in the PERAHIA ARTICLE.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 50:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Subject to the foregoing objections, Lilly will direct Plaintiff within its production to the study protocols and final study reports for each trial discussed in the PERAHIA ARTICLE.

**REQUEST FOR PRODUCTION NO. 51:**

Please produce the raw data, including but not limited to the case report forms for each of the CYMBALTA trials discussed in the PERAHIA ARTICLE.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 51:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope. Lilly further objects to this Request to this extent that it seeks personal health information protected under HIPAA and other privacy laws. Production of raw data and case report forms requires labor intensive review of voluminous files in order to screen out or redact confidential patient information. Lilly has produced the PERAHIA ARTICLE, documents from Dr. David Perahia's email files that were responsive to certain Cymbalta-related and discontinuation-related search terms, and all Cymbalta study protocols and final study reports that could be located through a reasonably diligent search, including those from the nine trials discussed in the PERAHIA ARTICLE. Plaintiff has access to those documents, which aggregate and summarize raw data and information contained in the case report forms. To the extent that Plaintiff seeks documents beyond those described above, the burden of complying with the Request outweighs Plaintiff's need for documents of this scope.

**REQUEST FOR PRODUCTION NO. 52:**

Please produce all DOCUMENTS reflecting the amount of compensation given to the authors of the PERAHIA ARTICLE, including but not limited to non-listed authors in the final publication.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 52:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope. Lilly also objects to this Request and its use of "compensation" and "non-listed authors"



as vague and ambiguous. Lilly further objects to this Request on behalf of Dr. David Perahia who opposes disclosure of his compensation on privacy grounds. *See Hexum/Herrera* actions, Deposition of David Perahia, Dec. 12, 2014, at 26:18-28:13.

**REQUEST FOR PRODUCTION NO. 53:**

Please produce a copy of the articles identified in Interrogatories Nos. 18 & 19.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 53:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope. Lilly refers Plaintiff to its objections to Interrogatories Nos. 18 and 19. To the extent that Lilly provides citations for the journal publications requested in Interrogatories Nos. 18 and 19, Lilly further objects to this Request as those articles are available to Plaintiff in the public domain.

**REQUEST FOR PRODUCTION NO. 54:**

Please produce all DOCUMENTS reflecting LILLY's involvement in the drafting, editing, and publication of those articles identified in Interrogatories Nos. 18 & 19.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 54:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also refers Plaintiff to its objections to Interrogatories Nos. 18 and 19. To the extent that Lilly provides citations for the journal publications requested in Interrogatories Nos. 18 and 19, those articles contain disclosure statements concerning Lilly's sponsorship. To the extent that this Request for "all DOCUMENTS" requires Lilly to expand its efforts to a company-wide search, the burden of complying with the Request outweighs Plaintiff's need for

documents of this scope. Lilly also objects to the Request to the extent it is duplicative of Request Nos. 48 and 49.

**REQUEST FOR PRODUCTION NO. 55:**

Please produce all DOCUMENTS reflecting the amount of compensation given to the authors of those articles identified in Interrogatories Nos. 18 &19, including but not limited to compensation associated with the article's publication. In lieu of producing these documents, Plaintiff would accept an Excel chart listing each author and the total amount of compensation received by that author by LILLY, by year.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 55:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request and its use of "compensation" as vague and ambiguous. Lilly also refers Plaintiff to its objections to Interrogatories Nos. 18 and 19. Lilly further objects to this Request to the extent it is duplicative of Request No. 52.

**REQUEST FOR PRODUCTION NO. 56:**

Please produce all DOCUMENTS reflecting any communications between LILLY and the authors of the articles identified in Interrogatories Nos. 18 &19 concerning discontinuation or withdrawal symptoms upon discontinuation of any SSRI or SNRI, including but not limited to CYMBALTA, Effexor, Prozac, Paxil and Zoloft.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 56:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which

Plaintiff has access. Lilly also objects to this Request as not limited to documents concerning Cymbalta. The Complaint does not allege that Plaintiff was treated with Effexor, Prozac, Paxil or Zoloft, and third parties, not Lilly, manufacture Effexor, Paxil, and Zoloft. As such, documents relating to Effexor, Prozac, Paxil, and Zoloft are irrelevant in this matter. Lilly also refers Plaintiff to its objections to Interrogatories Nos. 18 and 19. To the extent that this Request for “all DOCUMENTS” requires Lilly to expand its efforts to a company-wide search, the burden of complying with the Request outweighs Plaintiff’s need for documents of this scope. Lilly further objects to this Request to the extent it is duplicative of Request Nos. 48, 49, 54, and 55.

**REQUEST FOR PRODUCTION NO. 57:**

Please produce all DOCUMENTS reflecting any COMMUNICATIONS between LILLY and Mario Fava concerning discontinuation or withdrawal symptoms upon discontinuation of any SSRI or SNRI, including but not limited to CYMBALTA, Effexor, Prozac, Paxil and Zoloft.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 57:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents in the possession of third parties. Lilly also objects to this Request as not limited to documents relating to Cymbalta. Dr. Maurizio Fava is not a current or former Lilly employee. The Complaint does not allege that Plaintiff was treated with Effexor, Prozac, Paxil, or Zoloft, and third parties, not Lilly, manufacture Effexor, Paxil, and Zoloft. As such, this Request seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence. Moreover, Lilly objects to this Request to the extent Plaintiff already has or may obtain access to Dr. Fava’s third-party production in the *Hexum/Herrera* actions.

**REQUEST FOR PRODUCTION NO. 58:**

Please produce all DOCUMENTS reflecting any COMMUNICATIONS between LILLY and Jerrold Rosenbaum concerning discontinuation or withdrawal symptoms upon discontinuation of any SSRI or SNRI, including but not limited to CYMBALTA, Effexor, Prozac, Paxil and Zoloft.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 58:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents in the possession of third parties. Lilly also objects to this Request as not limited to documents relating to Cymbalta. Dr. Jerrold Rosenbaum is not a current or former Lilly employee. The Complaint does not allege that Plaintiff was treated with Effexor, Prozac, Paxil, or Zoloft, and third parties, not Lilly, manufacture Effexor, Paxil, and Zoloft. As such, this Request seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence. Moreover, Lilly objects to this Request to the extent Plaintiff already has or may obtain access to Dr. Rosenbaum's third-party production in the *Hexum/Herrera* actions.

**REQUEST FOR PRODUCTION NO. 59:**

Please produce all DOCUMENTS reflecting any COMMUNICATIONS between LILLY and Peter Haddad concerning discontinuation or withdrawal symptoms upon discontinuation of any SSRI or SNRI, including but not limited to CYMBALTA, Effexor, Prozac, Paxil and Zoloft.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 59:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents in the possession of third parties or previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request as not

limited to documents relating to Cymbalta. Dr. Peter Haddad is not a current or former Lilly employee. The Complaint does not allege that Plaintiff was treated with Effexor, Prozac, Paxil, or Zoloft, and third parties, not Lilly, manufacture Effexor, Paxil, and Zoloft. As such, this Request seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence. During his work with Lilly, Dr. Haddad communicated principally with Dr. Perahia, whose emails that are responsive to certain Cymbalta-related and discontinuation-related search terms have been produced by Lilly. Plaintiff has access to those documents.

**REQUEST FOR PRODUCTION NO. 60:**

Please produce all DOCUMENTS reflecting any communications between LILLY and Alan Schatzberg concerning discontinuation or withdrawal symptoms upon discontinuation of any SSRI or SNRI, including but not limited to CYMBALTA, Effexor, Prozac, Paxil and Zoloft.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 60:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents in the possession of third parties. Lilly also objects to this Request as not limited to documents relating to Cymbalta. Dr. Alan Schatzberg is not a current or former Lilly employee. The Complaint does not allege that Plaintiff was treated with Effexor, Prozac, Paxil, or Zoloft, and third parties, not Lilly, manufacture Effexor, Paxil, and Zoloft. As such, this Request seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence.

**REQUEST FOR PRODUCTION NO. 61:**

Please produce all CYMBALTA clinical trials wherein DEAEs or withdrawal symptoms were measured, noted, calculated, or where data concerning DEAEs or withdrawal was obtained,

regardless of whether measuring DEAEs or withdrawal symptoms was part of the trial's original protocol. Please note this request is not limited in time (i.e., pre-approval or post-approval), geography (i.e., location of the study or clinical trial), type (i.e., placebo-controlled, active-controlled, or open), authorship (i.e., LILLY-sponsored or conducted by a third-party), or whether the trial was FDA-sanctioned. This request seeks all DEAE or withdrawal clinical data within LILLY's possession.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 61:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents in the possession of third parties or previously produced by Lilly in productions to which Plaintiff has access. Lilly has produced all Lilly-sponsored clinical trials relating to Cymbalta that were located through a reasonably diligent search of the documents within its possession, custody, and control. Plaintiff has access to these documents.

**REQUEST FOR PRODUCTION NO. 62:**

Please produce any presentations, PowerPoint presentations, memoranda, product brochures / marketing materials, and/or audio/video recordings, used by LILLY with regard to CYMBALTA that mention the potential risk of withdrawal or discontinuation from CYMBALTA.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 62:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly has produced email files from nine Lilly employees who had significant involvement in or responsibility for Cymbalta that were responsive to certain Cymbalta-related and discontinuation-related search terms. Lilly has also produced its Form

2253 submissions containing Cymbalta marketing materials and advertisements. Those productions contain numerous examples of PowerPoint presentations, memoranda, promotional materials, and other materials concerning Cymbalta. To the extent this request requires a company-wide search for additional materials, the burden of complying with this Request outweighs Plaintiff's need for documents of this scope.

**REQUEST FOR PRODUCTION NO. 63:**

Please produce all Continuing Medical Education ("CME") presentations or programs, including those DOCUMENTS given to attendees of CMEs, sponsored or created by YOU that mention DEAEs, withdrawal, discontinuation, dependence or addiction, whether related to CYMBALTA or not, including but not limited to presentations that reference Prozac / fluoxetine and/or Effexor / venlafaxine.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 63:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request as it is not limited to documents relating to Cymbalta and therefore seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence. The Complaint does not allege that Plaintiff was treated with Prozac or Effexor, and a third party, not Lilly, manufactures Effexor. As such, documents relating to Prozac/fluoxetine or Effexor/venlafaxine are irrelevant in this matter. Furthermore, Lilly has already produced materials responsive to this request, including some Prozac-related CME materials, and Plaintiff has access to those documents. Finally, Lilly objects to this Request to the extent it is duplicative of Request No. 62.

**REQUEST FOR PRODUCTION NO. 64:**

Please produce DOCUMENTS which list, in whatever interval those lists were compiled, key opinion leaders / thought leaders related to CYMBALTA.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 64:**

Lilly objects to this Request as overly broad as to time and refers Plaintiff to its objections to Interrogatory No. 4.

**REQUEST FOR PRODUCTION NO. 65:**

Please produce all DOCUMENTS reflecting any agreement with a key opinion leader / thought leader related to CYMBALTA.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 65:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and further objects to the term “agreement” as vague and ambiguous. Any contract with a key opinion leader or thought leader is irrelevant to the allegations of the Complaint and not likely to lead to the discovery of admissible evidence.

**REQUEST FOR PRODUCTION NO. 66:**

Please produce all DOCUMENTS reflecting any compensation given to a key opinion leader / thought leader related to CYMBALTA.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 66:**

Lilly objects to this Request as overly broad as to time and refers Plaintiff to its objections to Interrogatory No. 5.



**V. SALES AND MARKETING**

**REQUEST FOR PRODUCTION NO. 67:**

Please produce all television commercials for CYMBALTA.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 67:**

Lilly objects to this Request as overly broad as to time and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Those productions include transcripts and stills of television commercials for Cymbalta.

**REQUEST FOR PRODUCTION NO. 68:**

Please produce all radio commercials for CYMBALTA.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 68:**

Lilly objects to this Request as overly broad as to time and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Those productions include transcripts of radio commercials for Cymbalta.

**REQUEST FOR PRODUCTION NO. 69:**

Please produce all advertisements in magazines for CYMBALTA.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 69:**

Lilly objects to this Request as overly broad as to time and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Those productions include English-language magazine advertisements for Cymbalta.

**REQUEST FOR PRODUCTION NO. 70:**

Please produce all advertisements on the internet for CYMBALTA.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 70:**

Lilly objects to this Request as overly broad as to time and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access.

**REQUEST FOR PRODUCTION NO. 71:**

Please produce all press releases ever issued by LILLY with regard to CYMBALTA.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 71:**

Lilly objects to this Request as overly broad as to time and scope and to the extent it is not limited to documents relating to any alleged discontinuation-emergent adverse events potentially arising from Cymbalta treatment. Lilly also objects to this Request to the extent it seeks documents that are publicly available.

**REQUEST FOR PRODUCTION NO. 72:**

Please produce all COMMUNICATIONS with WebMD regarding CYMBALTA.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 72:**

Lilly objects to this Request as overly broad as to subject matter. The Complaint contains no mention of WebMD, and this request therefore seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence.

**REQUEST FOR PRODUCTION NO. 73:**

Please produce every marketing plan, including all drafts, for CYMBALTA, regardless of whether that plan was prepared internally or by a third-party.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 73:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Subject to the foregoing objections, Lilly will direct Plaintiff within its prior production to its annual brand plans concerning Cymbalta.

**REQUEST FOR PRODUCTION NO. 74:**

Please produce any report or DOCUMENT reflecting the effectiveness of LILLY's marketing campaigns for CYMBALTA.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 74:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request and its use of "reflecting the effectiveness of Lilly's marketing campaign" as vague and ambiguous and to the extent it seeks documents that are of limited relevance to Plaintiff's treatment. Lilly further objects to this Request to the extent that it is duplicative of Request No. 73 and refers Plaintiff to its objections to Request No. 73.

**REQUEST FOR PRODUCTION NO. 75:**

Please produce every business plan, including all drafts, for CYMBALTA, regardless of whether that plan was prepared internally or by a third-party.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 75:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which

Plaintiff has access. Lilly also objects to this Request to the extent that it is duplicative of Request No. 73 and refers Plaintiff to its objections to Request No. 73

**REQUEST FOR PRODUCTION NO. 76:**

Please produce every launch plan, including all drafts, for CYMBALTA, regardless of whether that plan was prepared internally or by a third-party.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 76:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Plaintiff's treatment with Cymbalta began in 2012, more than seven years after the launch of Cymbalta, and Lilly objects to this Request to the extent that it seeks documents remote in time and of limited relevance to Plaintiff's treatment. Lilly further objects to this Request to the extent that it is duplicative of Request No. 73 and refers Plaintiff to its objections to Request No. 73.

**REQUEST FOR PRODUCTION NO. 77:**

Please produce all COMMUNICATIONS between LILLY and any third-party marketing company or consultant concerning CYMBALTA's direct-to-consumer marketing that discusses, in any way, WITHDRAWAL.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 77:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope. Plaintiff has produced submissions to FDA concerning Cymbalta direct-to-consumer marketing, annual brand plans concerning Cymbalta marketing strategy, Cymbalta advertisements and promotional materials, and other related communications to the extent

captured in the emails of nine Lilly employees responsive to certain Cymbalta-related and discontinuation-related search terms. Plaintiff has access to those documents. To the extent this request requires Lilly to additionally produce “all COMMUNICATIONS between Lilly and any third-party” covering those same topics, the burden of complying with this Request outweighs Plaintiff’s need for documents of this scope.

**REQUEST FOR PRODUCTION NO. 78:**

Please produce all COMMUNICATIONS between LILLY and any third-party marketing company or consultant concerning CYMBALTA’s direct-to-consumer marketing that discusses, in any way, once-a-day versus twice-a-day dosing.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 78:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope. Plaintiff has produced submissions to FDA concerning Cymbalta direct-to-consumer marketing, annual brand plans concerning Cymbalta marketing strategy, Cymbalta advertisements and promotional materials, and other related communications to the extent captured in the emails of nine Lilly employees responsive to certain Cymbalta-related and discontinuation-related search terms. Plaintiff has access to those documents. To the extent this request requires Lilly to additionally produce “all COMMUNICATIONS between Lilly and any third-party” covering those same topics, the burden of complying with this Request outweighs Plaintiff’s need for documents of this scope. Moreover, Lilly objects to this request to the extent that it is duplicative of Request No. 77.

**REQUEST FOR PRODUCTION NO. 79:**

Please produce all DOCUMENTS reflecting any contract or agreement between LILLY and a third-party company or consultant related to CYMBALTA's direct-to-consumer marketing.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 79:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and further objects to the term "agreement" as vague and ambiguous. Any contract with a third-party company or consultant is irrelevant to the allegations of the Complaint and Lilly therefore objects to this Request as not likely to lead to the discovery of admissible evidence.

**REQUEST FOR PRODUCTION NO. 80:**

Please produce all market surveys and focus group results / summaries for CYMBALTA.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 80:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request as it is not limited to documents relating to any alleged discontinuation-emergent adverse events potentially arising from Cymbalta treatment therefore seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence.

**REQUEST FOR PRODUCTION NO. 81:**

Please produce all versions of materials and DOCUMENTS, including but not limited to videos or audio recordings, used to train LILLY pharmaceutical representatives about CYMBALTA.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 81:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Subject to the foregoing objections, Lilly will direct Plaintiff within its prior productions to its sales training modules and standard operating procedures (“SOPs”) for pharmaceutical representatives on Cymbalta and discontinuation.

**REQUEST FOR PRODUCTION NO. 82:**

Please produce DOCUMENTS reflecting LILLY’s policies and practices regarding communicating with a MEDICAL PROFESSIONAL by a LILLY pharmaceutical representative.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 82:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request as not limited to documents relating to Cymbalta. Subject to the foregoing objections, Lilly will direct Plaintiff within its prior productions to Lilly’s SOPs on pharmaceutical representatives’ communication with medical professionals.

**REQUEST FOR PRODUCTION NO. 83:**

Please produce exemplars of samples of CYMBALTA that were left with MEDICAL PROFESSIONALS by LILLY pharmaceutical representatives.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 83:**

Lilly objects to this Request as overly broad as to time and scope. Lilly also objects to this Request as not limited to documents that would have been viewed by Plaintiff’s physicians.

**REQUEST FOR PRODUCTION NO. 84:**

Please produce all marketing or promotional materials used with MEDICAL PROFESSIONALS by LILLY pharmaceutical representatives, regardless of whether that material was left with the MEDICAL PROFESSIONAL or not.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 84:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request as not limited to documents relating to Cymbalta or discontinuation-emergent adverse events. As part of its production of Form 2253 submissions, Lilly has produced Cymbalta-related marketing and promotional materials, including those shown to medical professionals. Plaintiff has access to these documents.

**REQUEST FOR PRODUCTION NO. 85:**

Please produce DOCUMENTS reflecting LILLY's policies and practices regarding the showing of medical journal articles to MEDICAL PROFESSIONALS by a LILLY pharmaceutical representative.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 85:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request as not limited to documents relating to Cymbalta. Subject to the foregoing objections, Lilly will direct Plaintiff within its prior productions to Lilly's SOPs on pharmaceutical representatives' communication with medical professionals.



**REQUEST FOR PRODUCTION NO. 86:**

Please produce all medical journal articles used by LILLY pharmaceutical representatives to promote CYMBALTA.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 86:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request as not limited to documents relating to discontinuation-emergent adverse events. As part of its production of Form 2253 submissions, Lilly has produced Cymbalta-related marketing and promotional materials, including reprints of journal articles shown to medical professionals. Plaintiff has access to these documents.

**REQUEST FOR PRODUCTION NO. 87:**

Please produce all DOCUMENTS that reflect COMMUNICATIONS between LILLY and the media about CYMBALTA and WITHDRAWAL.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 87:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope. Lilly also objects to this Request to the extent it seeks documents that are publicly available. Moreover, Lilly objects to this Request to the extent it is duplicative of Request No. 71.

**VI. CLIENT-SPECIFIC REQUESTS**

**REQUEST FOR PRODUCTION NO. 88:**

Please produce all DOCUMENTS reflecting any COMMUNICATION between LILLY and the following:

- Dr. Navera R. Ahmad  
Virginia Hospital Center  
1701 N. George Mason Drive  
Arlington, VA 22205  
(703) 525-3069
- Dr. Thonia Hafez Gab-Allah (retired)  
(571) 232-1309
- Dr. Jayasree Patla  
Alexandria Healthcare  
6303 Little River Turnpike, Suite 160  
Alexandria, VA 22312  
(703) 658-2650

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 88:**

Lilly objects to this Request as not limited to documents relating to Cymbalta.

**REQUEST FOR PRODUCTION NO. 89:**

Please produce the custodial file, including but not limited to employment agreements, termination agreements, performance reviews, self-reviews, W-2s, and bonus amounts, for each pharmaceutical representative who called upon the following:

- Dr. Navera R. Ahmad  
Virginia Hospital Center  
1701 N. George Mason Drive  
Arlington, VA 22205  
(703) 525-3069
- Dr. Thonia Hafez Gab-Allah (retired)  
(571) 232-1309
- Dr. Jayasree Patla  
Alexandria Healthcare  
6303 Little River Turnpike, Suite 160  
Alexandria, VA 22312  
(703) 658-2650

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 89:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope. Lilly also objects to this Request as it is not limited to documents relating to Cymbalta or any alleged discontinuation-emergent adverse events potentially arising from Cymbalta treatment and therefore seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence.

**REQUEST FOR PRODUCTION NO. 90:**

Please produce all records, entries, or other data from YOUR pharmaceutical representative database, or any other electronic database used to track sales calls to physicians, regarding each and every sales call made to following:

- Dr. Navera R. Ahmad  
Virginia Hospital Center  
1701 N. George Mason Drive  
Arlington, VA 22205  
(703) 525-3069
- Dr. Thonia Hafez Gab-Allah (retired)  
(571) 232-1309
- Dr. Jayasree Patla  
Alexandria Healthcare  
6303 Little River Turnpike, Suite 160  
Alexandria, VA 22312  
(703) 658-2650

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 90:**

Lilly objects to this Request as not limited to documents relating to Cymbalta.

**REQUEST FOR PRODUCTION NO. 91:**

Please produce all DOCUMENTS reflecting any compensation, gifts, payments, honoraria, or consulting fees given by LILLY to the following:

- Dr. Navera R. Ahmad  
Virginia Hospital Center  
1701 N. George Mason Drive  
Arlington, VA 22205  
(703) 525-3069
- Dr. Thonia Hafez Gab-Allah (retired)  
(571) 232-1309
- Dr. Jayasree Patla  
Alexandria Healthcare  
6303 Little River Turnpike, Suite 160  
Alexandria, VA 22312  
(703) 658-2650

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 91:**

Lilly objects to this Request as not limited to documents relating to Cymbalta.

**REQUEST FOR PRODUCTION NO. 92:**

Please produce any written agreements, contracts, liability releases, or other legal documents that have been drafted and/or executed between LILLY or any third-party representing LILLY and the following:

- Dr. Navera R. Ahmad  
Virginia Hospital Center  
1701 N. George Mason Drive  
Arlington, VA 22205  
(703) 525-3069
- Dr. Thonia Hafez Gab-Allah (retired)  
(571) 232-1309
- Dr. Jayasree Patla  
Alexandria Healthcare  
6303 Little River Turnpike, Suite 160

Alexandria, VA 22312  
(703) 658-2650

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 92:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope. Lilly also objects to this Request as any contract with Drs. Ahmad, Gab-Allah, or Patla is irrelevant to the allegations of the Complaint and not likely to lead to the discovery of admissible evidence.

**REQUEST FOR PRODUCTION NO. 93:**

Please produce all DOCUMENTS, including but not limited to marketing materials, brochures, sales aids, “slim jims,” “skiffs,” clinical trials / medical journal articles, PowerPoint presentations, etc., that were given or shown by LILLY pharmaceutical representatives to the following:

- Dr. Navera R. Ahmad  
Virginia Hospital Center  
1701 N. George Mason Drive  
Arlington, VA 22205  
(703) 525-3069
- Dr. Thonia Hafez Gab-Allah (retired)  
(571) 232-1309
- Dr. Jayasree Patla  
Alexandria Healthcare  
6303 Little River Turnpike, Suite 160  
Alexandria, VA 22312  
(703) 658-2650

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 93:**

Lilly objects to this Request as not limited to documents relating to Cymbalta and to the extent records of any documents or marketing materials given or shown by Lilly pharmaceutical representatives to Drs. Ahmad, Gab-Allah, or Patla are not contained in Lilly’s sales database.

**REQUEST FOR PRODUCTION NO. 94:**

Please produce all DOCUMENTS reflecting participation in any LILLY-sponsored educational or sales program involving CYMBALTA by the following:

- Dr. Navera R. Ahmad  
Virginia Hospital Center  
1701 N. George Mason Drive  
Arlington, VA 22205  
(703) 525-3069
- Dr. Thonia Hafez Gab-Allah (retired)  
(571) 232-1309
- Dr. Jayasree Patla  
Alexandria Healthcare  
6303 Little River Turnpike, Suite 160  
Alexandria, VA 22312  
(703) 658-2650

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 94:**

Lilly has no objection.

**REQUEST FOR PRODUCTION NO. 95:**

Please produce, for the request above, all materials, including but not limited to PowerPoint presentations, syllabus, medical journal articles, summaries, agendas, etc., provided to or shown as part of the LILLY-sponsored program.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 95:**

Lilly objects to this Request as not limited to documents relating to Cymbalta.

**REQUEST FOR PRODUCTION NO. 96:**

Please produce all records in YOUR possession related to Plaintiff. Please note that this request is in no way limited to medical or psychiatric records, but includes any DOCUMENTS obtained from a third-party by LILLY about the Plaintiff.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 96:**

Lilly objects to this Request to the extent it seeks documents that Lilly has collected or will collect about Plaintiff after the date of the Complaint. As part of investigating the factual allegations of the Complaint, Lilly may collect information about Plaintiff and objects to this Request to the extent it requires Lilly to turn over the fruits of its own investigative efforts. Plaintiff's counsel is better suited to gather information from its own client.

**REQUEST FOR PRODUCTION NO. 97:**

Please produce all DOCUMENTS reflecting any correspondence created in collecting the records described in the above request.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 97:**

Lilly objects to this Request to the extent it seeks documents or communications that would reveal Lilly's legal strategy in this action or are protected by attorney-client privilege, work product doctrine, or any other immunity.

**VII. OTHER REQUESTS**

**REQUEST FOR PRODUCTION NO. 98:**

Please produce all DOCUMENTS identified in YOUR answers to all of Plaintiff's Interrogatories.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 98:**

Lilly objects to this Request as overly broad as Lilly intends to identify categories of documents in answering Plaintiff's interrogatories, including many documents that Lilly has previously produced to which Plaintiff has access.

**REQUEST FOR PRODUCTION NO. 99:**

Please produce all DOCUMENTS from which YOU obtained answers in responding to all of Plaintiff's Interrogatories.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 99:**

Lilly objects to this Request as overly broad as Lilly intends to rely on categories of documents in answering Plaintiff's interrogatories, including many documents that Lilly has previously produced to which Plaintiff has access.

**REQUEST FOR PRODUCTION NO. 100:**

Please produce the custodial file, including but not limited to employment agreements, termination agreements, performance reviews, self-reviews, W-2s, and bonus amounts, for each individual presented by LILLY as a person most knowledgeable under Federal Rule of Civil Procedure 30(b)(6).

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 100:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request as it is not limited to documents relating to Cymbalta or any alleged discontinuation-emergent adverse events potentially arising from Cymbalta treatment and therefore seeks information that is neither relevant nor likely to lead to



the discovery of admissible evidence. Lilly has produced documents related to the topics on which its 30(b)(6) witnesses were previously deposed in the *Hexum/Herrera* actions, and Plaintiff has access to those documents. Lilly further objects to this Request as premature as Plaintiff has not yet noticed a deposition of a person most knowledgeable under Federal Rule of Civil Procedure 30(b)(6) in this action.

**REQUEST FOR PRODUCTION NO. 101:**

Please produce all electronic mail (“email”) for the individuals presented by LILLY as a person most knowledgeable under Federal Rule of Civil Procedure 30(b)(6), whether internal or external and whether on LILLY’s current computer operating system, on individual employees’ laptop computers, or archive systems, which contain at least one of the following terms:

**Cy!, dulo!, Aricclaim, Xeristar, Yentreve, Duzela, Dulane, Cymgen, Prozac, Fluox!, Paxil, Parox!, Zolofit, Sertra!, Celexa, Citalop!, Lexapro, Escitalop!, Effexor, venlafa!, Pristiq, desvenlafax!, milnacipr!, levomilnacipr!, SSRI!, SNRI!, or anti!,**

*and* at least one of the following terms:

**DEAE!, discon!, withd!, taper!, cold w/1turkey, addict!, habit!, paresth!, zap!, electric w/4 shock, dizz!, Rosenbaum, Schatzberg, Glenmullen, half-life, “missed dose,” downregu!, “greater than or equal to,” Perahia, enteric, or time-release.**

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 101:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request as it is not limited to documents relating to Cymbalta or any alleged discontinuation-emergent adverse events potentially arising from Cymbalta treatment and therefore seeks information that is neither relevant nor likely to lead to

the discovery of admissible evidence. Lilly has produced documents related to the topics on which its 30(b)(6) witnesses were previously deposed in the *Hexum/Herrera* actions, and Plaintiff has access to those documents. Lilly further objects to search terms such as “anti!”, “addict!”, “habit!”, “greater than or equal to”, or “delayed release” as overly broad and far beyond the scope of the allegations of the Complaint. Lilly further objects to this Request as premature as Plaintiff has not yet noticed a deposition of a person most knowledgeable under Federal Rule of Civil Procedure 30(b)(6) in this case.

**REQUEST FOR PRODUCTION NO. 102:**

Please produce all DOCUMENTS in LILLY’s possession, custody or control concerning any governmental investigations of LILLY in relation to CYMBALTA and, in any way, with WITHDRAWAL.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 102:**

Lilly is not aware of any governmental investigations of Lilly in relation to Cymbalta and discontinuation symptoms.

**REQUEST FOR PRODUCTION NO. 103:**

With respect to Lilly’s Patient Assistance and/or Lilly Cares Program for CYMBALTA, please produce all documents regarding Lilly’s decision to establish the program; its structure and budget; its criteria for deciding which patients qualify for the program; and any complaints, questions, or comments received from participants, physicians, or pharmacies.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 103:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope. The Complaint contains no allegations that Plaintiff participated in Lilly’s Patient

Assistance or Lilly Cares Program, and therefore this Request seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence.

**REQUEST FOR PRODUCTION NO. 104:**

Please produce all DOCUMENTS pertaining to Lilly's provision of CYMBALTA to Plaintiff, if applicable, as part of Lilly's Patient Assistance and/or Lilly Cares program.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 104:**

Lilly has no objection.

**REQUEST FOR PRODUCTION NO. 105:**

Please produce all Corporate Integrity Agreements LILLY has entered into with any government for any reason.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 105:**

Lilly objects to this Request as overly broad as it is not limited to documents related to Cymbalta and therefore seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence. Lilly further objects to this Request to the extent it seeks publicly available information. (See <http://www.lilly.com/Documents/CIA.pdf>)

Respectfully Submitted,

Dated: February 23, 2015

By: \_\_\_\_\_/s/  
Jeffrey T. Bozman (83679)  
Covington & Burling LLP  
One CityCenter  
850 Tenth Street, NW  
Washington, DC 20001  
Tel: (202) 662-5829  
Fax: (202) 778-5829  
*Counsel for Eli Lilly and Company*

**CERTIFICATE OF SERVICE**

I, Jeffrey T. Bozman, hereby certify that on the 23rd day of February, 2015, I have served Plaintiff's counsel in this action with a copy of Defendant's Objections to Plaintiff's First Set of Requests for Production by mailing a copy of the same by United States Mail, postage prepaid, and electronic mail to the following address:

Peter A. Miller  
**Miller Legal LLC**  
175 S. Pantops Drive, Third Floor  
Charlottesville, VA 2291  
Telephone (434) 529-6909  
Facsimile (888) 830-1488  
PMiller@MillerLegalLLC.com  
*Counsel for Janine Ali*

Dated: February 23, 2015

By:                     /s/                      
Jeffrey T. Bozman (83679)  
Covington & Burling LLP  
One CityCenter  
850 Tenth Street, NW  
Washington, DC 20001  
Tel: (202) 662-5829  
Fax: (202) 778-5829  
*Counsel for Eli Lilly and Company*

## Exhibit 1-C

**UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF VIRGINIA  
ALEXANDRIA DIVISION**

JANINE ALI

Plaintiff,

v.

ELI LILLY AND COMPANY, an Indiana  
corporation,

Defendant.

CASE NO.: 1:14-CV-01615

**DEFENDANT’S RESPONSES TO PLAINTIFF’S FIRST SET OF REQUESTS FOR  
PRODUCTION OF DOCUMENTS**

Defendant Eli Lilly and Company (“Defendant” or “Lilly”) hereby submits its responses to Plaintiff’s First Set of Requests for Production, as follows:

**GENERAL STATEMENT**

The following responses are subject to Lilly’s Objections to Plaintiff’s First Set of Requests for Production served on February 23, 2015 pursuant to Federal Rule of Civil Procedure 34 and Local Civil Rule 26 and, for the sake of brevity, not repeated herein. Lilly has not fully completed its investigation of the facts relating to this case, its discovery, or its preparation for trial. Both discovery and independent investigation are ongoing. Therefore, all responses contained herein are based solely upon such information and documents as are both presently available and specifically known to Lilly. Lilly reserves the right to supplement these responses as discovery and this investigation proceed. Lilly’s responses are in accordance with the requirements of the Federal Rules of Civil Procedure, the Local Rules, and any applicable Court Orders.

**SPECIFIC RESPONSES TO REQUESTS FOR PRODUCTION**

**I. FDA DOCUMENTS**

**REQUEST FOR PRODUCTION NO. 1:**

Please produce the Electronic Common Technical Document (eCTD) or equivalent electronic submission for all CYMBALTA indications, whether that indication was approved or denied, including but not limited to: Major Depressive Disorder (MDD), Generalized Anxiety Disorder (GAD), Neuropathic Pain from Diabetes, Chronic Pain, Chronic Musculoskeletal Pain, Fibromyalgia, MDD Maintenance, GAD Maintenance, and Stress Urinary Incontinence (SUI).

**RESPONSE TO REQUEST FOR PRODUCTION NO. 1:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly responds that its Investigational New Drug ("IND") submission and New Drug Application ("NDA") submissions to FDA for Cymbalta indications can be found in Lilly's existing production at CYM-00000001 - CYM-01725262; CYM-01737200 - CYM-01737203; CYM-01737265 - CYM-01757110; and CYM-01757111 - CYM-01758619.

**REQUEST FOR PRODUCTION NO. 2:**

Please produce the Summary Basis of Approval for CYMBALTA for the following indications: Major Depressive Disorder (MDD), Generalized Anxiety Disorder (GAD), Neuropathic Pain from Diabetes, Chronic Pain, Chronic Musculoskeletal Pain, Fibromyalgia, MDD Maintenance, and GAD Maintenance.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 2:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 3:**

Please produce all Periodic Safety Updates regarding CYMBALTA for the following indications: Major Depressive Disorder (MDD), Generalized Anxiety Disorder (GAD), Neuropathic Pain from Diabetes, Chronic Pain, Chronic Musculoskeletal Pain, Fibromyalgia, MDD Maintenance, and GAD Maintenance.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 3:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly responds that its Periodic Safety Update Reports can be found in its existing production at CYM-00715114 - CYM-00717615; CYM-00719282 - CYM-01102877; CYM-00861952 - CYM-00862115; CYM-00857864 - CYM-00860751; CYM-00947704- CYM-00951649; CYM-00963610 - CYM-009674548; CYM-01103692 - CYM-001106656; CYM-01099044 - CYM-01102877; CYM-01117943 - CYM-01122174; CYM-00131805 - CYM-00140607; CYM-00289558 - CYM-00299778; CYM-00331576 - CYM-00342389; and CYM-00512955 - CYM-00525732.

**REQUEST FOR PRODUCTION NO. 4:**

Please produce all Annual Safety Updates regarding CYMBALTA for the following indications: Major Depressive Disorder (MDD), Generalized Anxiety Disorder (GAD), Neuropathic Pain from Diabetes, Chronic Pain, Chronic Musculoskeletal Pain, Fibromyalgia, MDD Maintenance, and GAD Maintenance.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 4:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly refers Plaintiff to its response to Request No. 3



**REQUEST FOR PRODUCTION NO. 5:**

Please produce the electronic Investigational New Drug (“IND”) file for CYMBALTA.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 5:**

Subject to and without waiving its Objections to Plaintiff’s First Set of Requests for Production, Lilly refers Plaintiff to its response to Request No. 1.

**REQUEST FOR PRODUCTION NO. 6:**

Please produce all warning letters sent to YOU from the FDA regarding CYMBALTA.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 6:**

Subject to and without waiving its Objections to Plaintiff’s First Set of Requests for Production, Lilly responds that letters it received from FDA’s Division of Drug Marketing, Advertising, and Communications (“DDMAC”) regarding Cymbalta can be found in its existing production at CYM-01236531 - CYM-01236535; CYM-1250524 - CYM-01250531; and CYM-01735325 - CYM-01735329; CYM-01735321 - CYM-01735324. Additional letters are publicly available at

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/default.htm>

**REQUEST FOR PRODUCTION NO. 7:**

Please produce YOUR responses to all warning letters sent to YOU from the FDA regarding CYMBALTA.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 7:**

Subject to and without waiving its Objections to Plaintiff’s First Set of Requests for Production, Lilly responds that its responses to letters it received from FDA’s DDMAC

regarding Cymbalta can be found in its existing production at CYM-01737172; CYM-01258099 - CYM-01258103; CYM-01258154 - CYM-01258160; and CYM-01737181 - CYM-01737199; CYM-01737173 - CYM-01737177; CYM-01735315 - CYM-01735320; and CYM-01735309 - CYM-01735314.

**REQUEST FOR PRODUCTION NO. 8:**

Please produce the transcript of any FDA Advisory Committee meetings regarding CYMBALTA for any indication.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 8:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 9:**

Please produce any DOCUMENTS submitted to the FDA as part of any Advisory Committee meeting related to CYMBALTA.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 9:**

Lilly refers Plaintiff to its objections this Request.

**REQUEST FOR PRODUCTION NO. 10:**

Please produce any and all Form 483 and/or Warning Letters that YOU received from the FDA related to CYMBALTA.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 10:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly refers Plaintiff to its response to Request No. 6.

**REQUEST FOR PRODUCTION NO. 11:**

Please produce YOUR responses to all Form 483 and/or Warning Letters that YOU received from the FDA related to CYMBALTA.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 11:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly refers Plaintiff to its response to Request No. 7.

**REQUEST FOR PRODUCTION NO. 12:**

Please produce all DOCUMENTS reflecting any settlements, agreements, resolutions, fines, sanctions and/or additional regulatory actions that arose as a result of the Form 483 and/or Warning Letters that YOU received from the FDA related to CYMBALTA.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 12:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly refers Plaintiff to its responses to Requests Nos. 6 and 7. Beyond the resolutions described therein, there were no additional regulatory actions that arose as a result of letters Lilly received from DDMAC related to Cymbalta.

**REQUEST FOR PRODUCTION NO. 13:**

Please produce all DOCUMENTS related to any COMMUNICATIONS with the FDA about CYMBALTA containing any of the following terms (or any derivative term): DEAE, withdrawal, discontinuation or discontinuing, dependence, habit-forming, addiction, quitting, tapering, brain zaps, electric shock, down regulation, half-life, missed dose, "greater than or equal to," Perahia, Rosenbaum, or Schatzberg.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 13:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 14:**

Please produce all DOCUMENTS related to any COMMUNICATIONS with the FDA about Prozac or fluoxetine containing any of the following terms (or any derivative term): DEAE, withdrawal, discontinuation or discontinuing, dependence, habit-forming, addiction, quitting, tapering, brain zaps, electric shock, down regulation, half-life, missed dose, “greater than or equal to,” Perahia, Rosenbaum, or Schatzberg.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 14:**

Subject to and without waiving its Objections to Plaintiff’s First Set of Requests for Production, Lilly responds that documents relating to Prozac can be found in its existing production at CYMPRO-0000000001 - CYMPRO-0000053299.

**REQUEST FOR PRODUCTION NO. 15:**

Please produce all DOCUMENTS related to any COMMUNICATIONS with the FDA about Zyprexa or olanzapine containing any of the following terms (or any derivative term): DEAE, withdrawal, discontinuation or discontinuing, dependence, habit-forming, addiction, quitting, tapering, brain zaps, electric shock, down regulation, half-life, missed dose, “greater than or equal to,” Perahia, Rosenbaum, or Schatzberg.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 15:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 16:**

Please produce all DOCUMENTS reflecting COMMUNICATIONS with the FDA about the section of the US LABEL titled “Discontinuation of Treatment with Cymbalta.”

**RESPONSE TO REQUEST FOR PRODUCTION NO. 16:**

Subject to and without waiving its Objections to Plaintiff’s First Set of Requests for Production, Lilly refers Plaintiff to its response to Request No. 1.

**REQUEST FOR PRODUCTION NO. 17:**

Please produce all DOCUMENTS reflecting COMMUNICATIONS with the FDA about the sections of the US LABEL titled “Dosage and Administration” or “Medication Administration” or “Information for Patients” (depending on year).

**RESPONSE TO REQUEST FOR PRODUCTION NO. 17:**

Subject to and without waiving its Objections to Plaintiff’s First Set of Requests for Production, Lilly refers Plaintiff to its responses to Requests Nos. 1 and 16.

**REQUEST FOR PRODUCTION NO. 18:**

Please produce all DOCUMENTS that reflect COMMUNICATIONS between LILLY and the FDA concerning LILLY’s Medical Information Letters, or similar letters, concerning the potential risk of withdrawal or discontinuation from CYMBALTA.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 18:**

Subject to and without waiving its Objections to Plaintiff’s First Set of Requests for Production, Lilly responds that medical information letters concerning Cymbalta and discontinuation-emergent adverse events can be found in its existing production at CYM-01727818 - CYM-01727884 and CYM-01766604 - CYM-01766611.

**REQUEST FOR PRODUCTION NO. 19:**

Please produce all COMMUNICATIONS between YOU and the FDA concerning the half-life of CYMBALTA.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 19:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly refers Plaintiff to its responses to Requests Nos. 1, 16, and 17.

**REQUEST FOR PRODUCTION NO. 20:**

Please produce all COMMUNICATIONS between YOU and the FDA concerning the enteric coating of CYMBALTA.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 20:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly refers Plaintiff to its responses to Requests Nos. 1, 16, 17, and 19.

**REQUEST FOR PRODUCTION NO. 21:**

Please produce a copy of each FDA-approved version of the package insert for CYMBALTA used by LILLY since it began marketing CYMBALTA in the United States.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 21:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly responds Lilly refers Plaintiff to Attachment E, which identifies the Bates numbers corresponding to each FDA-approved version of the Cymbalta package insert that could be located through a reasonably diligent search. Additional FDA-approved versions of the Cymbalta package insert are publicly available here:

<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Overview&>

DrugName=CYMBALTA&CFID=7507737&CFTOKEN=e8433ca4c6d9e77f-EE76B6D9-D59C-F73B-4B4ACFD7754D8B36

**REQUEST FOR PRODUCTION NO. 22:**

Please produce a copy of each version of the LABEL for CYMBALTA in each foreign country wherein CYMBALTA was approved for marketing in that country.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 22:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly responds that it will produce responsive documents that can be identified through a reasonably diligent search of its BLUE and REGULUS databases, which include approved labeling for Cymbalta submitted to the repositories by Lilly's global affiliates since November 2008.

**REQUEST FOR PRODUCTION NO. 23:**

Please produce the electronic Adverse Event Reporting database for CYMBALTA.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 23:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly refers Plaintiff to Attachment B, which provides the Bates numbers corresponding to reports made to FDA of adverse events potentially linked to Cymbalta, including so-called "MedWatch" forms. Lilly further refers Plaintiff to CYM-02055041-CYM-02055073, which constitutes Cymbalta postmarketing adverse event data from the Lilly Safety System for serious, unlisted events coded with at least one of the terms "drug withdrawal convulsions," "drug withdrawal headache," "drug withdrawal syndrome," "withdrawal hypertension," or "withdrawal syndrome."

**II. INTERNAL COMMUNICATIONS ABOUT CYMBALTA**

**REQUEST FOR PRODUCTION NO. 24:**

Please produce all DOCUMENTS reflecting LILLY's internal COMMUNICATIONS and/or deliberations concerning the section of the US CYMBALTA LABEL titled "Discontinuation of Treatment with Cymbalta," including not limited to all emails, memorandums, drafts, comments, edits, redlines, or discussions about those edits of those sections of the US CYMBALTA LABEL.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 24:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 25:**

Please produce all DOCUMENTS reflecting LILLY's internal COMMUNICATIONS and/or deliberations concerning the section of the US CYMBALTA LABEL titled "Dosage and Administration" or "Medication Administration" or "Information for Patients" (depending on year), including not limited to all emails, memorandums, drafts, comments, edits, redlines, or discussions about those edits of the that section of the US CYMBALTA LABEL.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 25:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 26:**

Please produce all DOCUMENTS reflecting LILLY's internal COMMUNICATIONS and/or deliberations concerning the following sentences in the US CYMBALTA LABEL as it was approved in 2004, including but not limited to all emails, memorandums, drafts, comments, edits, redlines, or discussions about those edits: "Duloxetine should be swallowed whole and



should not be chewed or crushed, nor should the contents be sprinkled on food or mixed with liquids. All of these might affect the enteric coating.”

**RESPONSE TO REQUEST FOR PRODUCTION NO. 26:**

Lilly refers Plaintiff to its objections this Request.

**REQUEST FOR PRODUCTION NO. 27:**

Please produce all DOCUMENTS that reflect LILLY’s reason for changing the US LABEL concerning “Discontinuation of Treatment with Cymbalta” in 2008 from “the following symptoms occurred at a rate greater than or equal to 2%” to “the following symptoms occurred at a rate greater than or equal to 1%.”

**RESPONSE TO REQUEST FOR PRODUCTION NO. 27:**

Subject to and without waiving its Objections to Plaintiff’s First Set of Requests for Production, Lilly refers Plaintiff to its response to Interrogatory No. 14.

**REQUEST FOR PRODUCTION NO. 28:**

Please produce all DOCUMENTS that reflect LILLY’s reason for adding to the 2009 US CYMBALTA LABEL “or tapered” in the context of “Following abrupt ... discontinuation ...” in the section titled “Discontinuation of Treatment with Cymbalta.”

**RESPONSE TO REQUEST FOR PRODUCTION NO. 28:**

Subject to and without waiving its Objections to Plaintiff’s First Set of Requests for Production, Lilly refers Plaintiff to its response to Interrogatory No. 15.

**REQUEST FOR PRODUCTION NO. 29:**

Please produce all DOCUMENTS that reflect LILLY's reason for changing the US CYMBALTA LABEL in 2012 from "the following symptoms occurred at a rate greater than or equal to 1%" to "at 1% or greater" in the section titled "Discontinuation of Treatment with Cymbalta."

**RESPONSE TO REQUEST FOR PRODUCTION NO. 29:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 30:**

Please produce all DOCUMENTS that reflect LILLY's reason for creating CYMBALTA as capsules containing enteric-coated pellets of duloxetine hydrochloride.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 30:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 31:**

Please produce all DOCUMENTS reflecting LILLY's internal COMMUNICATIONS and/or deliberations concerning the design of CYMBALTA as enteric-coated pellets contained within a capsule.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 31:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 32:**

Please produce all DOCUMENTS reflecting LILLY's internal COMMUNICATIONS and/or deliberations concerning the development of a dosage of CYMBALTA below 20mg.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 32:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 33:**

Please produce all DOCUMENTS reflecting LILLY's internal COMMUNICATIONS and/or deliberations concerning the development of CYMBALTA as a scored tablet.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 33:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 34:**

Please produce all memoranda, presentations, and/or reports, whether prepared internally or provided to LILLY by a third-party, that discuss, in any way, CYMBALTA and WITHDRAWAL.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 34:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly responds that it has already produced a significant amount of documents responsive to this request and such documents can be found in Lilly's existing production, and Lilly refers Plaintiff to the following documents as examples: CYM-01928754 - CYM-01928834; CYM-01952646 - CYM-01952676; CYM-02156153 - CYM-02156171; CYM-01952953 - CYM-01962959; CYM-01782498 - CYM-01782503

**REQUEST FOR PRODUCTION NO. 35:**

Please produce all electronic mail ("email") for the individuals identified in Interrogatory Nos. 1 & 3, whether internal or external and whether on LILLY's current computer operating

system, on individual employees' laptop computers, or archive systems, which contain at least one of the following terms:

**Cy!, dulo!, Aricclaim, Xeristar, Yentreve, Duzela, Dulane, Cymgen, Prozac, Fluox!, Paxil, Parox!, Zoloft, Sertra!, Celexa, Citalop!, Lexapro, Escitalop!, Effexor, venlafa!, Pristiq, desvenlafax!, milnacipr!, levomilnacipr!, SSRI!, SNRI!, or anti!,**

*and* at least one of the following terms:

**DEAE!, discon!, withd!, taper!, cold w/1turkey, addict!, habit!, paresth!, zap!, electric w/4 shock, dizz!, Rosenbaum, Schatzberg, Glenmullen, half-life, "missed dose," downregu!, "greater than or equal to," Perahia, enteric, pellets, "delayed release."**

**RESPONSE TO REQUEST FOR PRODUCTION NO. 35:**

Lilly refers Plaintiff to its objections to this Request and its objections to Interrogatories Nos. 1 and 3.

**REQUEST FOR PRODUCTION NO. 36:**

Please produce all DOCUMENTS that reflect LILLY's internal COMMUNICATIONS and/or deliberations concerning any and all letters used by LILLY to respond to inquiries regarding CYMBALTA and DEAEs, discontinuation, withdrawal, dependence, or addiction.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 36:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 37:**

Please produce all DOCUMENTS that reflect LILLY's internal COMMUNICATIONS and/or deliberations concerning any of LILLY's Medical Information Letters, or similar letters, concerning the potential risk of withdrawal or discontinuation from CYMBALTA.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 37:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly refers Plaintiff to its response to Request No. 18.

**REQUEST FOR PRODUCTION NO. 38:**

Please produce all minutes of meetings of any LILLY committee, working group, department, board, etc. where CYMBALTA and WITHDRAWAL were discussed.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 38:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 39:**

Please produce all DOCUMENTS that reflect LILLY's internal COMMUNICATIONS and/or deliberations concerning why the rate of WITHDRAWAL reflected in the PERAHIA article was not included in the US LABEL.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 39:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 40:**

Please produce all DOCUMENTS that reflect LILLY's internal COMMUNICATIONS and/or deliberations concerning why the rate of WITHDRAWAL reflected in the PERAHIA article was included in the European LABEL.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 40:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly refers Plaintiff to CYM-01865850 - CYM-01865854 and its response to Interrogatory No. 17.

**REQUEST FOR PRODUCTION NO. 41:**

Please produce all DOCUMENTS that reflect LILLY's internal COMMUNICATIONS concerning discontinuation or withdrawal symptoms upon discontinuation of Effexor, including but not limited to any discussion concerning the language contained in the US Effexor LABEL concerning WITHDRAWAL.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 41:**

Lilly refers Plaintiff to its objections to this Request.

**III. COMMUNICATIONS WITH MEDICAL PROFESSIONALS**

**REQUEST FOR PRODUCTION NO. 42:**

Please produce any "Dear Healthcare Professional" or similar letters to doctors, pharmacies or other groups, organizations about CYMBALTA.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 42:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly responds that its Dear Healthcare Professional letter concerning Cymbalta can be found in its existing production at CYM-01737200 - CYM-01737201.

**REQUEST FOR PRODUCTION NO. 43:**

Please produce all DOCUMENTS that contain a record or description of COMMUNICATIONS to LILLY from MEDICAL PROFESSIONALS or the public, including but not limited to call logs, inquiring about CYMBALTA that mention DEAEs, withdrawal, discontinuation or discontinuing, dependence, habit-forming, addiction, quitting, tapering, brain zaps, electric shock, down regulation, half-life (or any related or derivative terms).

**RESPONSE TO REQUEST FOR PRODUCTION NO. 43:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly responds that documents reflecting communications from health care professionals and consumers can be found in Lilly's existing production at CYM-02777356 - CYM-02777616.

**REQUEST FOR PRODUCTION NO. 44:**

Please produce any and all letters used by LILLY to respond to inquiries regarding CYMBALTA and DEAEs, discontinuation, withdrawal, dependence, or addiction.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 44:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly refers Plaintiff to its response to Request No. 18.

**REQUEST FOR PRODUCTION NO. 45:**

Please produce a copy of each and every version of LILLY's "Medical Information Letter" or similar letters to doctors, pharmacies or other groups, organizations or entities discussing the potential risk of withdrawal or discontinuation from CYMBALTA.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 45:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly refers Plaintiff to its responses to Requests Nos. 18 and 44.

**REQUEST FOR PRODUCTION NO. 46:**

Please produce all DOCUMENTS that identify MEDICAL PROFESSIONALS to whom LILLY sent a Medical Information Letter concerning the potential risk of withdrawal or discontinuation from CYMBALTA (e.g., an Excel spreadsheet or Access spreadsheet).

**RESPONSE TO REQUEST FOR PRODUCTION NO. 46:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 47:**

Please produce any and all DOCUMENTS that reflect each inquiry from a MEDICAL PROFESSIONAL concerning Cymbalta and withdrawal or discontinuation, including but not limited to written letters, telephone calls, online requests, sales representative relay.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 47:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly refers Plaintiff to its response to Request No. 43.

**IV. MEDICAL LITERATURE AND CONTINUING MEDICAL EDUCATION**

**REQUEST FOR PRODUCTION NO. 48:**

Please produce all publication plans for CYMBALTA, whether prepared internally or by a third-party.



**RESPONSE TO REQUEST FOR PRODUCTION NO. 48:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly responds that it will produce publication plans for Cymbalta that can be located through a reasonably diligent search.

**REQUEST FOR PRODUCTION NO. 49:**

Please produce all DOCUMENTS reflecting LILLY's involvement in the drafting, editing, and publication the PERAHIA ARTICLE, including but not limited to all email communications, article drafts, and publication plans relating to the PERAHIA ARTICLE.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 49:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 50:**

Please produce the study protocol and final study reports for each of the CYMBALTA trials discussed in the PERAHIA ARTICLE.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 50:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly responds that the study protocols and final study reports for each of the Cymbalta trials discussed in the PERAHIA ARTICLE can be found in Lilly's existing production at CYM-01020818 - CYM-01033963; CYM-01054242 - CYM-01057304; CYM-01033964 - CYM-01035948; CYM-01028897 - CYM-01030817; CYM-01057305 - CYM-01059489; CYM-01026706 - CYM-01028896; CYM-01059490 - CYM-01078316; CYM-00870792 - CYM-00876204; that CYM-01493802 - CYM-01531668.

**REQUEST FOR PRODUCTION NO. 51:**

Please produce the raw data, including but not limited to the case report forms for each of the CYMBALTA trials discussed in the PERAHIA ARTICLE.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 51:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 52:**

Please produce all DOCUMENTS reflecting the amount of compensation given to the authors of the PERAHIA ARTICLE, including but not limited to non-listed authors in the final publication.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 52:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 53:**

Please produce a copy of the articles identified in Interrogatories Nos. 18 & 19.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 53:**

Lilly refers Plaintiff to its objections to this Request and its objections to Interrogatories Nos. 18 and 19.

**REQUEST FOR PRODUCTION NO. 54:**

Please produce all DOCUMENTS reflecting LILLY's involvement in the drafting, editing, and publication of those articles identified in Interrogatories Nos. 18 & 19.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 54:**

Lilly refers Plaintiff to its objections to this Request and its objections to Interrogatories Nos. 18 and 19.

**REQUEST FOR PRODUCTION NO. 55:**

Please produce all DOCUMENTS reflecting the amount of compensation given to the authors of those articles identified in Interrogatories Nos. 18 &19, including but not limited to compensation associated with the article's publication. In lieu of producing these documents, Plaintiff would accept an Excel chart listing each author and the total amount of compensation received by that author by LILLY, by year.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 55:**

Lilly refers Plaintiff to its objections to this Request and its objections to Interrogatories Nos. 18 and 19.

**REQUEST FOR PRODUCTION NO. 56:**

Please produce all DOCUMENTS reflecting any communications between LILLY and the authors of the articles identified in Interrogatories Nos. 18 &19 concerning discontinuation or withdrawal symptoms upon discontinuation of any SSRI or SNRI, including but not limited to CYMBALTA, Effexor, Prozac, Paxil and Zoloft.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 56:**

Lilly refers Plaintiff to its objections to this Request and its objections to Interrogatories Nos. 18 and 19.

**REQUEST FOR PRODUCTION NO. 57:**

Please produce all DOCUMENTS reflecting any COMMUNICATIONS between LILLY and Mario Fava concerning discontinuation or withdrawal symptoms upon discontinuation of any SSRI or SNRI, including but not limited to CYMBALTA, Effexor, Prozac, Paxil and Zoloft.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 57:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly refers Plaintiff to Dr. Fava's third-party production: FAVA-001 - FAVA-144.

**REQUEST FOR PRODUCTION NO. 58:**

Please produce all DOCUMENTS reflecting any COMMUNICATIONS between LILLY and Jerrold Rosenbaum concerning discontinuation or withdrawal symptoms upon discontinuation of any SSRI or SNRI, including but not limited to CYMBALTA, Effexor, Prozac, Paxil and Zoloft.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 58:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly refers Plaintiff to Dr. Rosenbaum's third-party production: ROSENBAUM-0001 - ROSENBAUM-0014.

**REQUEST FOR PRODUCTION NO. 59:**

Please produce all DOCUMENTS reflecting any COMMUNICATIONS between LILLY and Peter Haddad concerning discontinuation or withdrawal symptoms upon discontinuation of any SSRI or SNRI, including but not limited to CYMBALTA, Effexor, Prozac, Paxil and Zoloft.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 59:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 60:**

Please produce all DOCUMENTS reflecting any communications between LILLY and Alan Schatzberg concerning discontinuation or withdrawal symptoms upon discontinuation of any SSRI or SNRI, including but not limited to CYMBALTA, Effexor, Prozac, Paxil and Zoloft.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 60:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 61:**

Please produce all CYMBALTA clinical trials wherein DEAEs or withdrawal symptoms were measured, noted, calculated, or where data concerning DEAEs or withdrawal was obtained, regardless of whether measuring DEAEs or withdrawal symptoms was part of the trial's original protocol. Please note this request is not limited in time (i.e., pre-approval or post-approval), geography (i.e., location of the study or clinical trial), type (i.e., placebo-controlled, active-controlled, or open), authorship (i.e., LILLY-sponsored or conducted by a third-party), or whether the trial was FDA-sanctioned. This request seeks all DEAE or withdrawal clinical data within LILLY's possession.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 61:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly refers Plaintiff to Attachment A, which identifies the Bates numbers corresponding to Cymbalta clinical trials located through a reasonably diligent search of Lilly's existing production. They are organized generally according to the NDA to which they relate and include, among others, clinical trials that measured discontinuation-emergent adverse events.

**REQUEST FOR PRODUCTION NO. 62:**

Please produce any presentations, PowerPoint presentations, memoranda, product brochures / marketing materials, and/or audio/video recordings, used by LILLY with regard to CYMBALTA that mention the potential risk of withdrawal or discontinuation from CYMBALTA.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 62:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly refers Plaintiff to its responses to Requests Nos. 34 and 67. Lilly further responds that responsive materials can be found in Lilly's existing production and refers Plaintiff to the following documents as examples: CYM-01754727 - CYM-01754761; CYM-01726950 - CYM-01726961; CYM-01726905 - CYM-01726916; and CYM-01743625 - CYM-01743650.

**REQUEST FOR PRODUCTION NO. 63:**

Please produce all Continuing Medical Education ("CME") presentations or programs, including those DOCUMENTS given to attendees of CMEs, sponsored or created by YOU that mention DEAEs, withdrawal, discontinuation, dependence or addiction, whether related to CYMBALTA or not, including but not limited to presentations that reference Prozac / fluoxetine and/or Effexor / venlafaxine.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 63:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly responds that materials from Lilly-sponsored Continuing Medical Education presentations or programs related to Cymbalta or Prozac can be found in Lilly's existing production and refers Plaintiff to the follow documents as examples: CYMPRO-0000053089 -

CYMPRO-0000053118; CYMPRO-0000053220 - CYMPRO-0000053253; CYMPRO-0000053254 - CYMPRO-0000053297; and CYM-02051103 - CYM-02051117.

**REQUEST FOR PRODUCTION NO. 64:**

Please produce DOCUMENTS which list, in whatever interval those lists were compiled, key opinion leaders / thought leaders related to CYMBALTA.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 64:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly responds that information about non-employee doctors associated with Lilly in relation to Cymbalta can be found in Faculty Reports, Contract Status Reports, and Activity Detail Reports that can be found within its existing production at CYM-02739356 - CYM-02777355.

**REQUEST FOR PRODUCTION NO. 65:**

Please produce all DOCUMENTS reflecting any agreement with a key opinion leader / thought leader related to CYMBALTA.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 65:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 66:**

Please produce all DOCUMENTS reflecting any compensation given to a key opinion leader / thought leader related to CYMBALTA.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 66:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly refers Plaintiff to its response to Request No. 64.

**V. SALES AND MARKETING**

**REQUEST FOR PRODUCTION NO. 67:**

Please produce all television commercials for CYMBALTA.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 67:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly refers Plaintiff to Attachment C, which identifies the Bates numbers corresponding to examples of Cymbalta advertisements, promotional materials, and related documents.

**REQUEST FOR PRODUCTION NO. 68:**

Please produce all radio commercials for CYMBALTA.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 68:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly refers Plaintiff to its response to Request No. 67.

**REQUEST FOR PRODUCTION NO. 69:**

Please produce all advertisements in magazines for CYMBALTA.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 69:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly refers Plaintiff to its response to Request No. 67.



**REQUEST FOR PRODUCTION NO. 70:**

Please produce all advertisements on the internet for CYMBALTA.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 70:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly refers Plaintiff to its response to Request No. 67.

**REQUEST FOR PRODUCTION NO. 71:**

Please produce all press releases ever issued by LILLY with regard to CYMBALTA.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 71:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly responds that Lilly press releases are publicly available at <http://lilly.mediaroom.com/>

**REQUEST FOR PRODUCTION NO. 72:**

Please produce all COMMUNICATIONS with WebMD regarding CYMBALTA.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 72:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 73:**

Please produce every marketing plan, including all drafts, for CYMBALTA, regardless of whether that plan was prepared internally or by a third-party.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 73:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly responds that brand plans for Cymbalta can be found in Lilly's existing

production and refers to the following documents as examples: CYM-01725585 - CYM-01725610; CYM-01725697 - CYM-01725756; CYM-01726046 - CYM-01726052; CYM-02302344 - CYM-02302350.

**REQUEST FOR PRODUCTION NO. 74:**

Please produce any report or DOCUMENT reflecting the effectiveness of LILLY's marketing campaigns for CYMBALTA.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 74:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 75:**

Please produce every business plan, including all drafts, for CYMBALTA, regardless of whether that plan was prepared internally or by a third-party.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 75:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly refers Plaintiff to its response to Request No. 73.

**REQUEST FOR PRODUCTION NO. 76:**

Please produce every launch plan, including all drafts, for CYMBALTA, regardless of whether that plan was prepared internally or by a third-party.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 76:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 77:**

Please produce all COMMUNICATIONS between LILLY and any third-party marketing company or consultant concerning CYMBALTA's direct-to-consumer marketing that discusses, in any way, WITHDRAWAL.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 77:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 78:**

Please produce all COMMUNICATIONS between LILLY and any third-party marketing company or consultant concerning CYMBALTA's direct-to-consumer marketing that discusses, in any way, once-a-day versus twice-a-day dosing.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 78:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 79:**

Please produce all DOCUMENTS reflecting any contract or agreement between LILLY and a third-party company or consultant related to CYMBALTA's direct-to-consumer marketing.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 79:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 80:**

Please produce all market surveys and focus group results / summaries for CYMBALTA.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 80:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly responds that it will produce market surveys and related materials concerning Cymbalta and discontinuation-emergent adverse events, if any, that can be located through a reasonably diligent search.

**REQUEST FOR PRODUCTION NO. 81:**

Please produce all versions of materials and DOCUMENTS, including but not limited to videos or audio recordings, used to train LILLY pharmaceutical representatives about CYMBALTA.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 81:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly refers Plaintiff to Attachment D, which identifies the Bates numbers corresponding to Lilly's standard operating procedures ("SOPs"). Lilly further refers Plaintiff to training materials for sales representatives relating to Cymbalta, which can be found in its existing production at CYM-01728139- CYM-01732494.

**REQUEST FOR PRODUCTION NO. 82:**

Please produce DOCUMENTS reflecting LILLY's policies and practices regarding communicating with a MEDICAL PROFESSIONAL by a LILLY pharmaceutical representative.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 82:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly refers Plaintiff to its response to Request No. 81.

**REQUEST FOR PRODUCTION NO. 83:**

Please produce exemplars of samples of CYMBALTA that were left with MEDICAL PROFESSIONALS by LILLY pharmaceutical representatives.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 83:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly responds that it will produce exemplars of the packaging and accompanying materials for samples of Cymbalta.

**REQUEST FOR PRODUCTION NO. 84:**

Please produce all marketing or promotional materials used with MEDICAL PROFESSIONALS by LILLY pharmaceutical representatives, regardless of whether that material was left with the MEDICAL PROFESSIONAL or not.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 84:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly refers Plaintiff to its response to Request No. 67.

**REQUEST FOR PRODUCTION NO. 85:**

Please produce DOCUMENTS reflecting LILLY's policies and practices regarding the showing of medical journal articles to MEDICAL PROFESSIONALS by a LILLY pharmaceutical representative.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 85:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly refers Plaintiff to its response to Request No. 81.

**REQUEST FOR PRODUCTION NO. 86:**

Please produce all medical journal articles used by LILLY pharmaceutical representatives to promote CYMBALTA.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 86:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly refers Plaintiff to its response to Request No. 81, which includes reprints of journal articles for use with medical professionals, for example CYM-01092327 - CYM-01092345 and CYM-01092356 - CYM-1092367.

**REQUEST FOR PRODUCTION NO. 87:**

Please produce all DOCUMENTS that reflect COMMUNICATIONS between LILLY and the media about CYMBALTA and WITHDRAWAL.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 87:**

Lilly refers Plaintiff to its objections to this Request.

**VI. CLIENT-SPECIFIC REQUESTS**

**REQUEST FOR PRODUCTION NO. 88:**

Please produce all DOCUMENTS reflecting any COMMUNICATION between LILLY and the following:

- Dr. Navera R. Ahmad  
Virginia Hospital Center  
1701 N. George Mason Drive  
Arlington, VA 22205  
(703) 525-3069
- Dr. Thonia Hafez Gab-Allah (retired)  
(571) 232-1309

- Dr. Jayasree Patla  
Alexandria Healthcare  
6303 Little River Turnpike, Suite 160  
Alexandria, VA 22312  
(703) 658-2650

**RESPONSE TO REQUEST FOR PRODUCTION NO. 88:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly responds that there are no documents indicating communication between Lilly and Drs. Ahmad, Gab-Allah, or Patla beyond contact with Lilly-affiliated sales representatives.

**REQUEST FOR PRODUCTION NO. 89:**

Please produce the custodial file, including but not limited to employment agreements, termination agreements, performance reviews, self-reviews, W-2s, and bonus amounts, for each pharmaceutical representative who called upon the following:

- Dr. Navera R. Ahmad  
Virginia Hospital Center  
1701 N. George Mason Drive  
Arlington, VA 22205  
(703) 525-3069
- Dr. Thonia Hafez Gab-Allah (retired)  
(571) 232-1309
- Dr. Jayasree Patla  
Alexandria Healthcare  
6303 Little River Turnpike, Suite 160  
Alexandria, VA 22312  
(703) 658-2650

**RESPONSE TO REQUEST FOR PRODUCTION NO. 89:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 90:**

Please produce all records, entries, or other data from YOUR pharmaceutical representative database, or any other electronic database used to track sales calls to physicians, regarding each and every sales call made to following:

- Dr. Navera R. Ahmad  
Virginia Hospital Center  
1701 N. George Mason Drive  
Arlington, VA 22205  
(703) 525-3069
- Dr. Thonia Hafez Gab-Allah (retired)  
(571) 232-1309
- Dr. Jayasree Patla  
Alexandria Healthcare  
6303 Little River Turnpike, Suite 160  
Alexandria, VA 22312  
(703) 658-2650

**RESPONSE TO REQUEST FOR PRODUCTION NO. 90:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly responds that it will produce documents that can be located through a reasonably diligent search tracking sales calls to Drs. Ahmad and Patla related to Cymbalta. There are no records indicating sales calls to Dr. Gab-Allah related to Cymbalta.

**REQUEST FOR PRODUCTION NO. 91:**

Please produce all DOCUMENTS reflecting any compensation, gifts, payments, honoraria, or consulting fees given by LILLY to the following:

- Dr. Navera R. Ahmad  
Virginia Hospital Center  
1701 N. George Mason Drive  
Arlington, VA 22205  
(703) 525-3069



- Dr. Thonia Hafez Gab-Allah (retired)  
(571) 232-1309
- Dr. Jayasree Patla  
Alexandria Healthcare  
6303 Little River Turnpike, Suite 160  
Alexandria, VA 22312  
(703) 658-2650

**RESPONSE TO REQUEST FOR PRODUCTION NO. 91:**

Lilly responds that there are no documents indicating that Lilly provided compensation to Drs. Ahmad, Gab-Allah, or Patla.

**REQUEST FOR PRODUCTION NO. 92:**

Please produce any written agreements, contracts, liability releases, or other legal documents that have been drafted and/or executed between LILLY or any third-party representing LILLY and the following:

- Dr. Navera R. Ahmad  
Virginia Hospital Center  
1701 N. George Mason Drive  
Arlington, VA 22205  
(703) 525-3069
- Dr. Thonia Hafez Gab-Allah (retired)  
(571) 232-1309
- Dr. Jayasree Patla  
Alexandria Healthcare  
6303 Little River Turnpike, Suite 160  
Alexandria, VA 22312  
(703) 658-2650

**RESPONSE TO REQUEST FOR PRODUCTION NO. 92:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 93:**

Please produce all DOCUMENTS, including but not limited to marketing materials, brochures, sales aids, “slim jims,” “skiffs,” clinical trials / medical journal articles, PowerPoint presentations, etc., that were given or shown by LILLY pharmaceutical representatives to the following:

- Dr. Navera R. Ahmad  
Virginia Hospital Center  
1701 N. George Mason Drive  
Arlington, VA 22205  
(703) 525-3069
- Dr. Thonia Hafez Gab-Allah (retired)  
(571) 232-1309
- Dr. Jayasree Patla  
Alexandria Healthcare  
6303 Little River Turnpike, Suite 160  
Alexandria, VA 22312  
(703) 658-2650

**RESPONSE TO REQUEST FOR PRODUCTION NO. 93:**

Subject to and without waiving its Objections to Plaintiff’s First Set of Requests for Production, Lilly responds that the information in its sales database does not indicate which marketing materials or other documents were shown to particular medical professionals.

**REQUEST FOR PRODUCTION NO. 94:**

Please produce all DOCUMENTS reflecting participation in any LILLY-sponsored educational or sales program involving CYMBALTA by the following:

- Dr. Navera R. Ahmad  
Virginia Hospital Center  
1701 N. George Mason Drive  
Arlington, VA 22205  
(703) 525-3069

- Dr. Thonia Hafez Gab-Allah (retired)  
(571) 232-1309
- Dr. Jayasree Patla  
Alexandria Healthcare  
6303 Little River Turnpike, Suite 160  
Alexandria, VA 22312  
(703) 658-2650

**RESPONSE TO REQUEST FOR PRODUCTION NO. 94:**

Lilly responds that there are no documents indicating that Drs. Ahmad, Gab-Allah, or Patla attended any Lilly-sponsored program.

**REQUEST FOR PRODUCTION NO. 95:**

Please produce, for the request above, all materials, including but not limited to PowerPoint presentations, syllabus, medical journal articles, summaries, agendas, etc., provided to or shown as part of the LILLY-sponsored program.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 95:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly refers Plaintiff to its response to Request No. 94.

**REQUEST FOR PRODUCTION NO. 96:**

Please produce all records in YOUR possession related to Plaintiff. Please note that this request is in no way limited to medical or psychiatric records, but includes any DOCUMENTS obtained from a third-party by LILLY about the Plaintiff.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 96:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly responds that it will produce records about Plaintiff maintained by Lilly prior

to the initiation of this lawsuit that can be located through a reasonably diligent search, but, because Plaintiffs have rejected the sharing of costs relating to medical record collection, Lilly will not be providing records obtained through the litigation medical collection process.

**REQUEST FOR PRODUCTION NO. 97:**

Please produce all DOCUMENTS reflecting any correspondence created in collecting the records described in the above request.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 97:**

Lilly refers Plaintiff to its objections to this Request.

**VII. OTHER REQUESTS**

**REQUEST FOR PRODUCTION NO. 98:**

Please produce all DOCUMENTS identified in YOUR answers to all of Plaintiff's Interrogatories.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 98:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 99:**

Please produce all DOCUMENTS from which YOU obtained answers in responding to all of Plaintiff's Interrogatories.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 99:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 100:**

Please produce the custodial file, including but not limited to employment agreements, termination agreements, performance reviews, self-reviews, W-2s, and bonus amounts, for each individual presented by LILLY as a person most knowledgeable under Federal Rule of Civil Procedure 30(b)(6).

**RESPONSE TO REQUEST FOR PRODUCTION NO. 100:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 101:**

Please produce all electronic mail (“email”) for the individuals presented by LILLY as a person most knowledgeable under Federal Rule of Civil Procedure 30(b)(6), whether internal or external and whether on LILLY’s current computer operating system, on individual employees’ laptop computers, or archive systems, which contain at least one of the following terms:

**Cy!, dulo!, Aricclaim, Xeristar, Yentreve, Duzela, Dulane, Cymgen, Prozac, Fluox!, Paxil, Parox!, Zolof, Sertra!, Celexa, Citalop!, Lexapro, Escitalop!, Effexor, venlafa!, Pristiq, desvenlafax!, milnacipr!, levomilnacipr!, SSRI!, SNRI!, or anti!,**

*and* at least one of the following terms:

**DEAE!, discon!, withd!, taper!, cold w/1turkey, addict!, habit!, paresth!, zap!, electric w/4 shock, dizz!, Rosenbaum, Schatzberg, Glenmullen, half-life, “missed dose,” downregu!, “greater than or equal to,” Perahia, enteric, or time-release.**

**RESPONSE TO REQUEST FOR PRODUCTION NO. 101:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 102:**

Please produce all DOCUMENTS in LILLY's possession, custody or control concerning any governmental investigations of LILLY in relation to CYMBALTA and, in any way, with WITHDRAWAL.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 102:**

Lilly is not aware of any governmental investigations of Lilly in relation to Cymbalta and discontinuation symptoms.

**REQUEST FOR PRODUCTION NO. 103:**

With respect to Lilly's Patient Assistance and/or Lilly Cares Program for CYMBALTA, please produce all documents regarding Lilly's decision to establish the program; its structure and budget; its criteria for deciding which patients qualify for the program; and any complaints, questions, or comments received from participants, physicians, or pharmacies.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 103:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 104:**

Please produce all DOCUMENTS pertaining to Lilly's provision of CYMBALTA to Plaintiff, if applicable, as part of Lilly's Patient Assistance and/or Lilly Cares program.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 104:**

Lilly responds that it has no records indicating that Plaintiff participated in LillyCares, and that Patient Assistance is not available for Cymbalta.

**REQUEST FOR PRODUCTION NO. 105:**

Please produce all Corporate Integrity Agreements LILLY has entered into with any government for any reason.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 105:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly refers Plaintiff to Lilly's corporate integrity agreement, which publicly available at <http://www.lilly.com/Documents/CIA.pdf>

Respectfully Submitted,

Dated: March 9, 2015

By:                     /s/                      
Jeffrey T. Bozman (83679)  
Covington & Burling LLP  
One CityCenter  
850 Tenth Street, NW  
Washington, DC 20001  
Tel: (202) 662-5829  
Fax: (202) 778-5829  
*Counsel for Eli Lilly and Company*

**CERTIFICATE OF SERVICE**

I, Jeffrey T. Bozman, hereby certify that on the 9th day of March, 2015, I have served Plaintiff's counsel in this action with a copy of Defendant's Objections to Plaintiff's First Set of Requests for Production by mailing a copy of the same by United States Mail, postage prepaid, and electronic mail to the following address:

Peter A. Miller  
**Miller Legal LLC**  
175 S. Pantops Drive, Third Floor  
Charlottesville, VA 2291  
Telephone (434) 529-6909  
Facsimile (888) 830-1488  
PMiller@MillerLegalLLC.com  
*Counsel for Janine Ali*

Dated: March 9, 2015

By:                     /s/                      
Jeffrey T. Bozman (83679)  
Covington & Burling LLP  
One CityCenter  
850 Tenth Street, NW  
Washington, DC 20001  
Tel: (202) 662-5829  
Fax: (202) 778-5829  
*Counsel for Eli Lilly and Company*



## Exhibit 2-A

**UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF VIRGINIA  
ALEXANDRIA DIVISION**

JANINE ALI,

Plaintiff,

v.

ELI LILLY AND COMPANY, an Indiana  
corporation,

Defendant.

**CASE NO. 1:14-CV-01615-GBL-TRJ**

**PLAINTIFF'S FIRST SET OF REQUESTS FOR ADMISSION**

**PROPOUNDING PARTY:** Plaintiff, Janine Ali

**RESPONDING PARTY:** Defendant Eli Lilly and Company

**SET NO.:** ONE

Plaintiff Janine Ali, by and through her attorneys, and pursuant to Federal Rule of Civil Procedure 26 and 36 request that Defendant Eli Lilly and Company ("Lilly") admit or deny following statements of fact, application of law to fact, and opinions about either, separately and fully in writing and under oath within thirty (30) days of service.

**DEFINITIONS**

1. "ALL" means "any and all" and the word "any" means "any and all."
2. The term "CYMBALTA" means duloxetine hydrochloride, including any other name or trademark under which it is sold, domestically *or* abroad, marketed or produced, including products sold, marketed, or produced by others if they do so with your permission, at your request, at your direction, with your acquiescence, and/or if you gain any benefit from their sales, marketing, or distribution.

3. The term “COMMUNICATION” means and refers to every method and manner of transmitting or receiving data, opinions, thoughts, inquiries, representations and other information, whether orally, in writing, electronically, or otherwise, between two or more persons or entities. Communications include drafts and other written information intended for communicating to another person, even if not ultimately transmitted to or received by another person.

4. The term “IDENTIFY” (in reference to a person) means to state, to the extent known, the person’s full name, present or last known address, telephone number, company title (to the extent applicable), and whether or not the person is currently an employee of LILLY (to the extent applicable).

5. The terms “CONCERNING,” “RELATING,” and/or “REGARDING” mean containing, alluding to, responding to, commenting upon, discussing, explaining, mentioning, analyzing, constituting, memorializing, comprising, repeating, incorporating, confirming, listing, evidencing, setting forth, summarizing, or characterizing, either directly or indirectly, in whole or in part.

6. The term “DEAE” means Discontinuation Emergent Adverse Event, and refers to any possible side effects or symptoms relating to discontinuing, withdrawing, or tapering from the use, consumption, or treatment with Cymbalta.

7. The term “WITHDRAWAL” includes discontinuation or tapering, as well as DEAEs, withdrawal symptoms, and any side effects of withdrawing, discontinuing, or tapering from CYMBALTA.

8. The term “DOCUMENT” shall have the broadest meaning possible under Rule 34 of the Federal Rules of Civil Procedure and includes all originals and drafts, in any and all

languages, of any nature whatsoever, in your possession, custody or control, regardless of where located, and include, but are not limited to, letters, correspondence, logs, drafts, contracts, prospective contracts, agreements, reports, records, studies, surveys, resolutions, tabulations, notes, summaries, memoranda, Electronically Stored Information (“ESI”), electronic mail (“email”), calendar or diary entries, handwritten notes, working papers, work sheets, spread sheets, diagrams, minutes of meetings, agendas, bulletins, periodicals, circulars, advertisements, notices, announcements, invoices, statements, checks (front and back), bank statements, ledgers, orders, vouchers, instructions, drawings, charts, graphs, manuals, brochures, pamphlets, schedules, telegrams, teletypes, photographs, audio tapes, voice-mail messages, videotapes, electronic recordings, facsimile transmissions, and information of whatever kind either stored on computers, including computer disks, hard drives and other media, or contained in any computer or information retrieval devices.

9. The terms “ELI LILLY,” “LILLY,” “YOU” or “YOUR” refer to Eli LILLY and Company, its respective officers, directors, employees, representatives, subsidiaries, and affiliates thereof, as well as all persons acting for, on behalf of, or in concert with Eli LILLY and Company’s behalf, including agents, attorneys, accountants, and investigators.

10. The term “FDA” means the United States Food & Drug Administration.

11. The term “INCLUDING” means “including, but not limited to.”

12. The term “LABEL” refers to the official prescribing information for the drug, including but not limited to the product insert and medication guides approved by the FDA or other foreign regulatory bodies.

13. The term “MEDICAL PROFESSIONAL” includes healthcare providers, prescribing doctors, non-prescribing doctors, physicians, pharmacists, nurses, and other

individuals who provide healthcare services.

14. The term “PERAHIA ARTICLE” refers to David G. Perahia, *et al.*, *Symptoms Following Abrupt Discontinuation of Duloxetine Treatment in Patients with Major Depressive Disorder*, 89 J. Affective Disorders 207-12 (2005).

15. The term “SNRI” means serotonin norepinephrine reuptake inhibitor.

16. The term “SSRI” means selective serotonin reuptake inhibitor.

17. The use of the terms “or,” “and,” and “and/or” should be construed conjunctively and disjunctively for the broadest possible meaning.

18. The term “person” or “people” includes individuals, corporations, partnerships, associations, and other bodies and entities, as well as their representatives, agents, employees and attorneys.

19. The terms “research,” “study,” or “analysis,” when used as a noun mean and refer to any research, analysis, study, report, evaluation or assessment. The term research when used as a verb means to research, analyze, study, report, evaluate, or assess.

20. The term “use” means to “employ something for a purpose,” “to do something habitually,” “to consume something,” “to manipulate,” “to benefit from,” as well as to allow others to “use,” or acquiesce in others’ “use.”

21. The singular use of any term or phrase includes its plural, and the plural of any term or phrase includes its singular.

22. The use of any tense of any verb shall also include within its meaning all other tenses of that verb.

### **INSTRUCTIONS**

If a matter is not admitted, the answer must specifically deny it or state in detail why

YOU cannot truthfully admit or deny it. A denial must fairly respond to the substance of the matter. When, in good-faith, YOUR answer requires a qualification or YOU can only deny part of a matter, the answer must specify the part admitted and qualify or deny the rest. YOU may assert lack of knowledge or information as a reason for failing to admit or deny only if YOU clearly state that YOU have made reasonable inquiry and that the information YOU possess or can readily obtain is insufficient to enable YOU to admit or deny.

### **REQUESTS FOR ADMISSION**

#### **REQUEST FOR PRODUCTION NO. 1:**

Admit that the gradual or sudden discontinuation of CYMBALTA can cause adverse symptoms resulting from the discontinuation of CYMBALTA.

#### **REQUEST FOR PRODUCTION NO. 2:**

Admit that the abrupt discontinuation of a daily dose of 20 mg of CYMBALTA can cause adverse symptoms resulting from the discontinuation of CYMBALTA.

#### **REQUEST FOR PRODUCTION NO. 3:**

Admit that the abrupt discontinuation of a daily dose of 30 mg of CYMBALTA can cause adverse symptoms resulting from the discontinuation of CYMBALTA.

#### **REQUEST FOR PRODUCTION NO. 4:**

Admit that the abrupt discontinuation of a daily dose of 40 mg of CYMBALTA can cause adverse symptoms resulting from the discontinuation of CYMBALTA.

#### **REQUEST FOR PRODUCTION NO. 5:**

Admit that the abrupt discontinuation of a daily dose of 60 mg of CYMBALTA can cause adverse symptoms resulting from the discontinuation of CYMBALTA.

**REQUEST FOR PRODUCTION NO. 6:**

Admit that CYMBALTA's risk of causing adverse symptoms resulting from discontinuation of CYMBALTA is something a reasonable prescriber would consider important in deciding whether to prescribe the medication.

**REQUEST FOR PRODUCTION NO. 7:**

Admit that CYMBALTA's risk of causing adverse symptoms resulting from discontinuation of CYMBALTA is something a reasonable person would consider important in deciding whether to purchase and ingest the medication.

**REQUEST FOR PRODUCTION NO. 8:**

Admit that the gradual or sudden discontinuation of CYMBALTA can cause nausea.

**REQUEST FOR PRODUCTION NO. 9:**

Admit that the gradual or sudden discontinuation of CYMBALTA can cause headaches.

**REQUEST FOR PRODUCTION NO. 10:**

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**REQUEST FOR PRODUCTION NO. 11:**

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**REQUEST FOR PRODUCTION NO. 12:**

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**REQUEST FOR PRODUCTION NO. 13:**

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**REQUEST FOR PRODUCTION NO. 14:**

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Admit that, between 2004 and 2011, LILLY obtained over \$17 billion in revenue from the sale of CYMBALTA within the United States.

**REQUEST FOR PRODUCTION NO. 19:**

Admit that CYMBALTA has a shorter half-life than Prozac.

**REQUEST FOR PRODUCTION NO. 20:**

Admit that CYMBALTA has a shorter half-life than Paxil.

**REQUEST FOR PRODUCTION NO. 21:**

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**REQUEST FOR PRODUCTION NO. 22:**

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**REQUEST FOR PRODUCTION NO. 25:**

Admit that the shorter the half-life of an SSRI or SNRI, the more frequent the occurrences of WITHDRAWAL.

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Admit that Daniel Kajdasz was an employee of LILLY when the PERAHIA ARTICLE was published.

**REQUEST FOR PRODUCTION NO. 27:**

Admit that Durisala Desai was an employee of LILLY when the PERAHIA ARTICLE was published.

**REQUEST FOR PRODUCTION NO. 28:**

Admit that Peter Haddad has received payments from LILLY for attending advisory boards, lecturing, and consultancy work.

**REQUEST FOR PRODUCTION NO. 29:**

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**REQUEST FOR PRODUCTION NO. 39:**

Admit that the work conducted in the PERAHIA ARTICLE was funded by LILLY.

**REQUEST FOR PRODUCTION NO. 40:**

Admit that the DEAEs measured in the PERAHIA ARTICLE were assessed by means of spontaneous reports rather than a symptom checklist.

**REQUEST FOR PRODUCTION NO. 41:**

Admit that use of a symptom checklist, instead of spontaneous reports, would be expected to produce higher incidence rates of DEAEs in the PERAHIA ARTICLE.

**REQUEST FOR PRODUCTION NO. 42:**

Admit that LILLY sponsored the clinical trial by Jerrold Rosenbaum et al, *Selective Serotonin Reuptake Inhibitor Discontinuation Syndrome: A Randomized Clinical Trial*, 44 BIOLOGICAL PSYCHIATRY 2, 77-87 (1998).

**REQUEST FOR PRODUCTION NO. 43:**

Admit that, in Jerrold Rosenbaum et al, *Selective Serotonin Reuptake Inhibitor Discontinuation Syndrome: A Randomized Clinical Trial*, 44 BIOLOGICAL PSYCHIATRY 2, 77-87 (1998), the researchers used a symptom checklist to tabulate DEAEs / withdrawal symptoms.

**REQUEST FOR PRODUCTION NO. 44:**

Admit that the information contained in the European Medicines Agency Summary of Product Information for CYMBALTA is accurate and true.

**REQUEST FOR PRODUCTION NO. 45:**

Admit that, in clinical trials, adverse events seen on abrupt treatment discontinuation of CYMBALTA occurred in approximately 45% of patients treated with CYMBALTA.

**REQUEST FOR PRODUCTION NO. 46:**

Admit that the following statement appears in the European Medicines Agency Summary of Product Information for CYMBALTA: “In clinical trials adverse events seen on abrupt treatment discontinuation occurred in approximately 45% of patients treated with Cymbalta and 23% of patients taking placebo.”

**REQUEST FOR PRODUCTION NO. 47:**

Admit that the following statement does not appear on the CYMBALTA LABEL: “In clinical trials adverse events seen on abrupt treatment discontinuation occurred in approximately 45% of patients treated with Cymbalta and 23% of patients taking placebo.”

**REQUEST FOR PRODUCTION NO. 48:**

Admit that at no time has LILLY’s direct-to-consumer advertising, i.e., television, newspapers, magazines, and/or radio, warned patients that abrupt discontinuation of CYMBALTA occurred in approximately 45% of patients treated with CYMBALTA.

**REQUEST FOR PRODUCTION NO. 49:**

Admit that the following statement appears in the European Medicines Agency Summary of Product Information for CYMBALTA: “It is therefore advised that duloxetine should be gradually tapered when discontinuing treatment over a period of no less than 2 weeks, according to the patient’s needs (see section 4.2).”

**REQUEST FOR PRODUCTION NO. 50:**

Admit that the CYMBALTA LABEL does not state that CYMBALTA should be

gradually tapered “over a period of no less than 2 weeks[.]”

**REQUEST FOR PRODUCTION NO. 51:**

Admit that the European Medicines Agency Summary of Product Information for CYMBALTA refers to “discontinuation-emergent adverse events” as “withdrawal symptoms.”

**REQUEST FOR PRODUCTION NO. 52:**

Admit that the following statement appears in the European Medicines Agency Summary of Product Information for CYMBALTA: Withdrawal symptoms “may be prolonged (2-3 months or more).”

**REQUEST FOR PRODUCTION NO. 53:**

Admit that the CYMBALTA LABEL does not estimate how long discontinuation-emergent adverse events will likely take to resolve following abrupt or tapered discontinuation of CYMBALTA.

**REQUEST FOR PRODUCTION NO. 54:**

Admit that the CYMBALTA LABEL does not indicate that some individuals may have withdrawal symptoms for 2-3 months or more.

**REQUEST FOR PRODUCTION NO. 55:**

Admit that the CYMBALTA LABEL does not specify what percentage of patients will likely experience at least one discontinuation-emergent adverse event upon abrupt or tapered discontinuation of CYMBALTA.

**REQUEST FOR PRODUCTION NO. 56:**

Admit that YOU, not the FDA, bear responsibility for the content of the CYMBALTA LABEL at all times.

**REQUEST FOR PRODUCTION NO. 57:**

Admit that the smallest approved dose for CYMBALTA is 20 mg.

**REQUEST FOR PRODUCTION NO. 58:**

Admit that CYMBALTA has an elimination half-life of about 12 hours (range 8 to 17 hours).

**REQUEST FOR PRODUCTION NO. 59:**

Admit that CYMBALTA should be swallowed whole and should not be chewed or crushed.

**REQUEST FOR PRODUCTION NO. 60:**

Admit that the CYMBALTA capsule should not be opened and its contents sprinkled on food or mixed with liquids.

**REQUEST FOR PRODUCTION NO. 61:**

Admit that opening a CYMBALTA capsule, or crushing or chewing the CYMBALTA capsule, might affect its enteric coating.

Dated: February 4, 2015

Respectfully submitted,

**MILLER LEGAL, LLC**

/s/ Brielle M. Hunt

Brielle M. Hunt  
Miller Legal, LLC  
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-and-

**BAUM HEDLUND ARISTEI & GOLDMAN,  
P.C.**

/s/ R. Brent Wisner

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Los Angeles, CA 90025

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Email: [rbwisner@baumgedlundlaw.com](mailto:rbwisner@baumgedlundlaw.com)

**CERTIFICATE OF SERVICE**

I hereby certify that on this 4<sup>th</sup> day of February, 2015, a true and correct copy of the foregoing **PLAINTIFF'S FIRST SET OF REQUESTS FOR ADMISSION** was served via Electronic Mail, upon the following:

Jeffrey Todd Bozman  
Brett C. Reynolds (pro hac vice)  
Michael X. Imbroscio (pro hac vice)  
Phyllis A. Jones (pro hac vice)  
**COVINGTON & BURLING LLP**  
One City Center  
850 Tenth Street, NW  
Washington, DC 20001  
Email: [jbozman@cov.com](mailto:jbozman@cov.com)  
Email: [breynolds@cov.com](mailto:breynolds@cov.com)  
Email: [mimbrosio@cov.com](mailto:mimbrosio@cov.com)  
Email: [pajones@cov.com](mailto:pajones@cov.com)

*Attorneys for Eli Lilly and Company*

/s/

\_\_\_\_\_  
Samantha Jison



## Exhibit 2-B

**UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF VIRGINIA  
ALEXANDRIA DIVISION**

JANINE ALI

Plaintiff,

v.

ELI LILLY AND COMPANY, an Indiana  
corporation,

Defendant.

CASE NO.: 1:14-CV-01615-GBL-TRJ

**DEFENDANT’S OBJECTIONS TO PLAINTIFF’S AMENDED FIRST SET OF  
REQUESTS FOR ADMISSION**

Pursuant to Federal Rule of Civil Procedure 36, Defendant Eli Lilly and Company (“Defendant” or “Lilly”) hereby submits its objections to Plaintiff’s Amended First Set of Requests for Admission, as follows:

**OBJECTIONS TO DEFINITIONS AND INSTRUCTIONS**

1. Lilly objects to the definitions of the terms “ELI LILLY”, “LILLY”, “YOU”, and “YOUR” to the extent that they seek to extend these definitions to persons or entities other than the named Defendant in this litigation, Eli Lilly and Company, and purport to call for information or documents that are not in the possession, custody, or control of Eli Lilly and Company. For purposes of its objections and responses, Lilly will define “ELI LILLY”, “LILLY”, “YOU”, and “YOUR” to mean Eli Lilly and Company. Lilly will limit its responses to information and documents that are in the possession, custody, or control of Eli Lilly and Company.

2. Lilly objects to the definition of “DOCUMENT” to the extent that it imposes

obligations on Lilly beyond those in the Federal Rules of Civil Procedure.

**SPECIFIC OBJECTIONS TO REQUESTS FOR ADMISSION**

**REQUEST FOR ADMISSION NO. 1:**

Admit that the gradual or sudden discontinuation of CYMBALTA can cause adverse symptoms resulting from the discontinuation of CYMBALTA.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 1:**

Lilly objects to this Request for Admission because it is phrased as a tautology and the use of the term “cause” is vague and ambiguous as to the standard for causality. Lilly will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 2:**

Admit that the abrupt discontinuation of a daily dose of 20 mg of CYMBALTA can cause adverse symptoms resulting from the discontinuation of CYMBALTA.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 2:**

Lilly objects to this Request for Admission because it is phrased as a tautology and the use of the term “cause” is vague and ambiguous as to the standard for causality. Lilly will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 3:**

Admit that the abrupt discontinuation of a daily dose of 30 mg of CYMBALTA can cause adverse symptoms resulting from the discontinuation of CYMBALTA.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 3:**

Lilly objects to this Request for Admission because it is phrased as a tautology and the use of the term “cause” is vague and ambiguous as to the standard for causality. Lilly will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 4:**

Admit that the abrupt discontinuation of a daily dose of 40 mg of CYMBALTA can cause adverse symptoms resulting from the discontinuation of CYMBALTA.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 4:**

Lilly objects to this Request for Admission because it is phrased as a tautology and the use of the term “cause” is vague and ambiguous as to the standard for causality. Lilly will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 5:**

Admit that the abrupt discontinuation of a daily dose of 60 mg of CYMBALTA can cause adverse symptoms resulting from the discontinuation of CYMBALTA.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 5:**

Lilly objects to this Request for Admission because it is phrased as a tautology and the use of the term “cause” is vague and ambiguous as to the standard for causality. Lilly will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 6:**

Admit that CYMBALTA's risk of causing adverse symptoms resulting from discontinuation of CYMBALTA is something a reasonable prescriber would consider important in deciding whether to prescribe the medication.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 6:**

Lilly objects to this Request for Admission because the use of the term "important" is vague and ambiguous, and because the request as phrased is not subject to a simple "Admit" or "Deny" response because of the complex and individualized set of considerations that a medical provider and a patient must take into account when considering the nature of the underlying psychiatric or disease or pain condition and the range of possible medical treatments, especially given the varied and individualized efficacy for a given medicine. Lilly will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 7:**

Admit that CYMBALTA's risk of causing adverse symptoms resulting from discontinuation of CYMBALTA is something a reasonable person would consider important in deciding whether to purchase and ingest the medication.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 7:**

Lilly objects to this Request for Admission because the use of the term "important" is vague and ambiguous, and because the request as phrased is not subject to a simple "Admit" or "Deny" response because of the complex and individualized set of considerations that a medical provider and a patient must take into account when considering the nature of the underlying psychiatric or disease or pain condition and the range of possible medical treatments, especially

given the varied and individualized efficacy for a given medicine. Lilly will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 8:**

Admit that the gradual or sudden discontinuation of CYMBALTA can cause nausea.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 8:**

Lilly objects to this Request for Admission because the use of the term “cause” is vague and ambiguous as to the standard for causality. Lilly will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 9:**

Admit that the gradual or sudden discontinuation of CYMBALTA can cause headaches.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 9:**

Lilly objects to this Request for Admission because the use of the term “cause” is vague and ambiguous as to the standard for causality. Lilly will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 10:**

Admit that the gradual or sudden discontinuation of CYMBALTA can cause paresthesia.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 10:**

Lilly objects to this Request for Admission because the use of the term “cause” is vague and ambiguous as to the standard for causality. Lilly will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 11:**

Admit that the gradual or sudden discontinuation of CYMBALTA can cause nightmares.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 11:**

Lilly objects to this Request for Admission because the use of the term “cause” is vague and ambiguous as to the standard for causality. Lilly will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 12:**

Admit that the gradual or sudden discontinuation of CYMBALTA can cause insomnia.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 12:**

Lilly objects to this Request for Admission because the use of the term “cause” is vague and ambiguous as to the standard for causality. Lilly will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 13:**

Admit that the gradual or sudden discontinuation of CYMBALTA can cause anxiety.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 13:**

Lilly objects to this Request for Admission because the use of the term “cause” is vague and ambiguous as to the standard for causality. Lilly will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 14:**

Admit that the gradual or sudden discontinuation of CYMBALTA can cause hyperhidrosis.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 14:**

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**REQUEST FOR ADMISSION NO. 15:**

Admit that the gradual or sudden discontinuation of CYMBALTA can cause sensory disturbances.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 15:**

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**REQUEST FOR ADMISSION NO. 16:**

Admit that the gradual or sudden discontinuation of CYMBALTA can cause suicidal ideation.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 16:**

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**REQUEST FOR ADMISSION NO. 17:**

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**OBJECTIONS TO REQUEST FOR ADMISSION NO. 17:**

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**REQUEST FOR ADMISSION NO. 18:**

Admit that, between 2004 and 2011, LILLY obtained over \$17 billion in revenue from the sale of CYMBALTA within the United States.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 18:**

Lilly has no objection and will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 19:**

Admit that CYMBALTA has a shorter half-life than Prozac.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 19:**

Lilly has no objection and will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 20:**

Admit that CYMBALTA has a shorter half-life than Paxil.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 20:**

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**REQUEST FOR ADMISSION NO. 22:**

Admit that CYMBALTA has a shorter half-life than Celexa.

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Lilly has no objection and will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 23:**

Admit that CYMBALTA has a shorter half-life than Lexapro.

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Lilly has no objection and will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

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Admit that Effexor has a shorter half-life than CYMBALTA.

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Lilly has no objection and will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 25:**

Admit that the shorter the half-life of an SSRI or SNRI, the more frequent the occurrences of WITHDRAWAL.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 25:**

Lilly objects to this Request for Admission because its use of the term “occurrences of WITHDRAWAL” is vague and ambiguous given Plaintiff’s definition of “WITHDRAWAL.” Lilly will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 26:**

Admit that Daniel Kajdasz was an employee of LILLY when the PERAHIA ARTICLE was published.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 26:**

Lilly has no objection and will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

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Admit that Peter Haddad has received payments from LILLY for attending advisory boards, lecturing, and consultancy work.

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Lilly objects to this Request to the extent it simply seeks Lilly to affirm statements from a published article, which is not an appropriate use of Requests for Admission under Rule 36. Lilly will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

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**OBJECTIONS TO REQUEST FOR ADMISSION NO. 37:**

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**REQUEST FOR ADMISSION NO. 38:**

Admit that LILLY does not know how long it took for the discontinuation-emergent adverse events discussed in the PERAHIA ARTICLE to fully resolve.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 38:**

Lilly objects to this Request for Admission because its use of the term “fully” is vague and ambiguous, and further that the article referenced reported on a large number of trials involving hundreds of subjects and thus it is impossible to “Admit” or “Deny” such a blanket statement. Lilly will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 39:**

Admit that the work conducted in the PERAHIA ARTICLE was funded by LILLY.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 39:**

Lilly objects to this Request for Admission because its use of the phrase “work conducted” is vague and ambiguous. Lilly will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36..

**REQUEST FOR ADMISSION NO. 40:**

Admit that the DEAEs measured in the PERAHIA ARTICLE were assessed by means of spontaneous reports rather than a symptom checklist.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 40:**

Lilly objects to this Request for Admission to the extent it mischaracterizes Lilly’s assessment of DEAEs in clinical trials as not systematically evaluated, and because it simply seeks Lilly to affirm statements from a published article, which is not an appropriate use of



Requests for Admission under Rule 36. Lilly will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 41:**

Admit that use of a symptom checklist, instead of spontaneous reports, would be expected to produce higher incidence rates of DEAEs in the PERAHIA ARTICLE.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 41:**

Lilly objects to this Request for Admission to the extent it implies that the use of a symptom checklist to assess DEAEs in clinical trials would result in a more accurate measurement of the incidence of DEAEs than other methods of assessing DEAEs. Lilly will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 42:**

Admit that LILLY sponsored the clinical trial by Jerrold Rosenbaum et al, Selective Serotonin Reuptake Inhibitor Discontinuation Syndrome: A Randomized Clinical Trial, 44 BIOLOGICAL PSYCHIATRY 2, 77-87 (1998).

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 42:**

Lilly has no objection and will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 43:**

Admit that, in Jerrold Rosenbaum et al, Selective Serotonin Reuptake Inhibitor Discontinuation Syndrome: A Randomized Clinical Trial, 44 BIOLOGICAL PSYCHIATRY 2,

77-87 (1998), the researchers used a symptom checklist to tabulate DEAEs / withdrawal symptoms.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 43:**

Lilly has no objection and will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 44:**

Admit that the information contained in the European Medicines Agency Summary of Product Information for CYMBALTA is accurate and true.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 44:**

Lilly objects to this Request for Admission to the extent it implies that the information contained in the European Medicines Agency Summary of Product Characteristics for Cymbalta is the most comprehensive source of information concerning Cymbalta. Lilly will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 45:**

Admit that, in clinical trials, adverse events seen on abrupt treatment discontinuation of CYMBALTA occurred in approximately 45% of patients treated with CYMBALTA.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 45:**

Lilly has no objection and will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 46:**

Admit that the following statement appears in the European Medicines Agency Summary of Product Information for CYMBALTA: “In clinical trials adverse events seen on abrupt treatment discontinuation occurred in approximately 45% of patients treated with Cymbalta and 23% of patients taking placebo.”

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 46:**

Lilly has no objection and will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 47:**

Admit that the following statement does not appear on the CYMBALTA LABEL: “In clinical trials adverse events seen on abrupt treatment discontinuation occurred in approximately 45% of patients treated with Cymbalta and 23% of patients taking placebo.”

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 47:**

Lilly objects to this Request for Admission because its use of the term “LABEL” is vague and ambiguous given Plaintiff’s definition of “LABEL.”

**REQUEST FOR ADMISSION NO. 48:**

Admit that at no time has LILLY’s direct-to-consumer advertising, i.e., television, newspapers, magazines, and/or radio, warned patients that abrupt discontinuation of CYMBALTA occurred in approximately 45% of patients treated with CYMBALTA.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 48:**

Lilly objects to this Request as nonsensical and cannot reasonably respond under Rule 36.

**REQUEST FOR ADMISSION NO. 49:**

Admit that the following statement appears in the European Medicines Agency Summary of Product Information for CYMBALTA: “It is therefore advised that duloxetine should be gradually tapered when discontinuing treatment over a period of no less than 2 weeks, according to the patient’s needs (see section 4.2).”

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 49:**

Lilly has no objection and will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 50:**

Admit that the CYMBALTA LABEL does not state that CYMBALTA should be gradually tapered “over a period of no less than 2 weeks[.]”

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 50:**

Lilly objects to this Request for Admission because its use of the term “LABEL” is vague and ambiguous given Plaintiff’s definition of “LABEL.”

**REQUEST FOR ADMISSION NO. 51:**

Admit that the European Medicines Agency Summary of Product Information for CYMBALTA refers to “discontinuation-emergent adverse events” as “withdrawal symptoms.”

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 51:**

Lilly has no objection and will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 52:**

Admit that the following statement appears in the European Medicines Agency Summary of Product Information for CYMBALTA: Withdrawal symptoms “may be prolonged (2-3 months or more).”

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 52:**

Lilly has no objection and will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 53:**

Admit that the CYMBALTA LABEL does not estimate how long discontinuation-emergent adverse events will likely take to resolve following abrupt or tapered discontinuation of CYMBALTA.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 53:**

Lilly objects to this Request for Admission because its use of the term “LABEL” is vague and ambiguous given Plaintiff’s definition of “LABEL.”

**REQUEST FOR ADMISSION NO. 54:**

Admit that the CYMBALTA LABEL does not indicate that some individuals may have withdrawal symptoms for 2-3 months or more.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 54:**

Lilly objects to this Request for Admission because its use of the term “LABEL” is vague and ambiguous given Plaintiff’s definition of “LABEL.”

**REQUEST FOR ADMISSION NO. 55:**

Admit that the CYMBALTA LABEL does not specify what percentage of patients will likely experience at least one discontinuation-emergent adverse event upon abrupt or tapered discontinuation of CYMBALTA.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 55:**

Lilly objects to this Request for Admission because its use of the term “LABEL” is vague and ambiguous given Plaintiff’s definition of “LABEL.”

**REQUEST FOR ADMISSION NO. 56:**

Admit that YOU, not the FDA, bear responsibility for the content of the CYMBALTA LABEL at all times.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 56:**

Lilly objects to this Request for Admission because its use of the term “responsibility” is vague and ambiguous. Lilly further objects to this Request to the extent that it calls for a legal conclusion.

**REQUEST FOR ADMISSION NO. 57:**

Admit that the smallest approved dose for CYMBALTA is 20 mg.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 57:**

Lilly has no objection and will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 58:**

Admit that CYMBALTA has an elimination half-life of about 12 hours (range 8 to 17 hours).

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 58:**

Lilly has no objection and will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 59:**

Admit that CYMBALTA should be swallowed whole and should not be chewed or crushed.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 59:**

Lilly has no objection and will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 60:**

Admit that the CYMBALTA capsule should not be opened and its contents sprinkled on food or mixed with liquids.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 60:**

Lilly has no objection and will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 61:**

Admit that opening a CYMBALTA capsule, or crushing or chewing the CYMBALTA capsule, might affect its enteric coating.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 61:**

Lilly has no objection and will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

Respectfully Submitted,

Dated: February 23, 2015

By:                     /s/                      
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*Counsel for Eli Lilly and Company*



**CERTIFICATE OF SERVICE**

I, Jeffrey T. Bozman, hereby certify that on the 23rd day of February, 2015, I have served Plaintiff's counsel in this action with a copy of Defendant's Objections to Plaintiffs First Set of Requests for Admission by mailing a copy of the same by United States Mail, postage prepaid, and electronic mail to the following address:

Peter A. Miller  
**Miller Legal LLC**  
175 S. Pantops Drive, Third Floor  
Charlottesville, VA 2291  
Telephone (434) 529-6909  
Facsimile (888) 830-1488  
PMiller@MillerLegalLLC.com  
*Counsel for Janine Ali*

Dated: February 23, 2015

By:                     /s/                      
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*Counsel for Eli Lilly and Company*

## Exhibit 2-C

**UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF VIRGINIA  
ALEXANDRIA DIVISION**

JANINE ALI

Plaintiff,

v.

ELI LILLY AND COMPANY, an Indiana  
corporation,

Defendant.

CASE NO.: 1:14-CV-01615

**DEFENDANT'S RESPONSES TO PLAINTIFF'S AMENDED FIRST SET OF  
REQUESTS FOR ADMISSION**

Pursuant to Federal Rule of Civil Procedure 36, Defendant Eli Lilly and Company ("Defendant" or "Lilly") hereby submits its responses to Plaintiff's Amended First Set of Requests for Admission, as follows:

**GENERAL STATEMENT**

The following responses are subject to Lilly's Objections to Plaintiff's Amended First Set of Requests for Admission served on February 23, 2015 pursuant to Federal Rule of Civil Procedure 36 and Local Civil Rule 26 and, for the sake of brevity, not repeated herein. Lilly has not fully completed its investigation of the facts relating to this case, its discovery, or its preparation for trial. Both discovery and independent investigation are ongoing. Therefore, all responses contained herein are based solely upon such information and documents as are both presently available and specifically known to Lilly. Lilly reserves the right to supplement these responses as discovery and this investigation proceed. Lilly's responses are in accordance with

the requirements of the Federal Rules of Civil Procedure, the Local Rules, and any applicable Court Orders.

## **RESPONSES TO REQUESTS FOR ADMISSION**

### **REQUEST FOR ADMISSION NO. 1:**

Admit that the gradual or sudden discontinuation of CYMBALTA can cause adverse symptoms resulting from the discontinuation of CYMBALTA.

### **RESPONSE TO REQUEST FOR ADMISSION NO. 1:**

Subject to Lilly's Objections to Plaintiff's Amended Requests for Admissions, Lilly admits that in some patients who are treated with Cymbalta, the gradual or sudden discontinuation of Cymbalta can lead to certain adverse symptoms, as warned in the August 2004 United States Physician Package Insert ("U.S. label") for Cymbalta:

#### **WARNINGS**

...

If the decision has been made to discontinue treatment, medication should be tapered, as rapidly as is feasible, but with recognition that abrupt discontinuation can be associated with certain symptoms (see PRECAUTIONS and DOSAGE AND ADMINISTRATION, Discontinuing Cymbalta (duloxetine hydrochloride), for a description of the risks of discontinuation of Cymbalta).

\* \* \*

#### **PRECAUTIONS**

...

Discontinuation of Treatment with Cymbalta -- Discontinuation symptoms have been systematically evaluated in patients taking Cymbalta. Following abrupt discontinuation in placebo-controlled clinical trials of up to 9-weeks duration, the following symptoms occurred at a rate greater than or equal to 2% and at a significantly higher rate in duloxetine-treated patients compared to those discontinuing from placebo: dizziness; nausea; headache; paresthesia; vomiting; irritability; and nightmare.

During marketing of other SSRIs and SNRIs (serotonin and norepinephrine reuptake inhibitors), there have been spontaneous reports of adverse events occurring upon discontinuation of these drugs, particularly when abrupt, including the following: dysphoric mood, irritability, agitation, dizziness, sensory disturbances (e.g., paresthesias such as electric shock sensations), anxiety, confusion, headache, lethargy, emotional lability, insomnia, hypomania, tinnitus,

and seizures. Although these events are generally self-limiting, some have been reported to be severe.

Patients should be monitored for these symptoms when discontinuing treatment with Cymbalta. A gradual reduction in the dose rather than abrupt cessation is recommended whenever possible. If intolerable symptoms occur following a decrease in the dose or upon discontinuation of treatment, then resuming the previously prescribed dose may be considered. Subsequently, the physician may continue decreasing the dose but at a more gradual rate (see DOSAGE AND ADMINISTRATION).

\* \* \*

## **DOSAGE AND ADMINISTRATION**

...

### **Discontinuing Cymbalta (duloxetine hydrochloride)**

Symptoms associated with discontinuation of Cymbalta and other SSRIs and SNRIs have been reported (see PRECAUTIONS). Patients should be monitored for these symptoms when discontinuing treatment. A gradual reduction in the dose rather than abrupt cessation is recommended whenever possible. If intolerable symptoms occur following a decrease in the dose or upon discontinuation of treatment, then resuming the previously prescribed dose may be considered. Subsequently, the physician may continue decreasing the dose but at a more gradual rate.

This warning has remained largely unchanged since Cymbalta's initial FDA approval for the treatment of Major Depressive Disorder.

## **REQUEST FOR ADMISSION NO. 2:**

Admit that the abrupt discontinuation of a daily dose of 20 mg of CYMBALTA can cause adverse symptoms resulting from the discontinuation of CYMBALTA.

## **RESPONSE TO REQUEST FOR ADMISSION NO. 2:**

Subject to Lilly's Objections to Plaintiff's Amended Requests for Admissions, because Lilly has not comprehensively studied the abrupt discontinuation from the 20 mg/day dose of Cymbalta, and because this low dose is unlikely to present a similar profile than a fully therapeutic dose, denied.

**REQUEST FOR ADMISSION NO. 3:**

Admit that the abrupt discontinuation of a daily dose of 30 mg of CYMBALTA can cause adverse symptoms resulting from the discontinuation of CYMBALTA.

**RESPONSE TO REQUEST FOR ADMISSION NO. 3:**

Subject to Lilly's Objections to Plaintiff's Amended Requests for Admissions, Lilly admits that in some patients who are treated with Cymbalta, the abrupt discontinuation of a 30 mg/day dose of Cymbalta may be associated with certain adverse symptoms, which are listed in Cymbalta's U.S. label, but further notes that many such patients do not experience such symptoms upon discontinuation.

**REQUEST FOR ADMISSION NO. 4:**

Admit that the abrupt discontinuation of a daily dose of 40 mg of CYMBALTA can cause adverse symptoms resulting from the discontinuation of CYMBALTA.

**RESPONSE TO REQUEST FOR ADMISSION NO. 4:**

Subject to Lilly's Objections to Plaintiff's Amended Requests for Admissions, Lilly admits that in some patients who are treated with Cymbalta, the abrupt discontinuation of a 40 mg/day dose of Cymbalta is associated with certain adverse symptoms, which are listed in Cymbalta's U.S. label, but further notes that many such patients do not experience such symptoms upon discontinuation.

**REQUEST FOR ADMISSION NO. 5:**

Admit that the abrupt discontinuation of a daily dose of 60 mg of CYMBALTA can cause adverse symptoms resulting from the discontinuation of CYMBALTA.

**RESPONSE TO REQUEST FOR ADMISSION NO. 5:**

Subject to Lilly's Objections to Plaintiff's Amended Requests for Admissions, Lilly admits that in some patients who are treated with Cymbalta, the abrupt discontinuation of a 60 mg/day dose of Cymbalta is associated with certain adverse symptoms, which are listed in Cymbalta's U.S. label, but further notes that many such patients do not experience such symptoms upon discontinuation.

**REQUEST FOR ADMISSION NO. 6:**

Admit that CYMBALTA's risk of causing adverse symptoms resulting from discontinuation of CYMBALTA is something a reasonable prescriber would consider important in deciding whether to prescribe the medication.

**RESPONSE TO REQUEST FOR ADMISSION NO. 6:**

Subject to Lilly's Objections to Plaintiff's Amended Requests for Admissions, Lilly admits that the risk of the occurrence of adverse symptoms upon discontinuation from an antidepressant like Cymbalta, which is stated in Cymbalta's U.S. label, is one of the many pieces of information that form part of the complex and individualized set of considerations that a medical provider might take into account in deciding whether to prescribe an antidepressant like Cymbalta, although it is likely to not be a major factor given the widespread understanding of this risk across similar medications and the primary goal of the physician to treat the depressive or pain condition affecting the patient at the time of the prescription decision.

**REQUEST FOR ADMISSION NO. 7:**

Admit that CYMBALTA's risk of causing adverse symptoms resulting from discontinuation of CYMBALTA is something a reasonable person would consider important in deciding whether to purchase and ingest the medication.

**RESPONSE TO REQUEST FOR ADMISSION NO. 7:**

Subject to Lilly's Objections to Plaintiff's Amended Requests for Admissions, Lilly cannot reasonably respond to this Request given the inherently unique situation presented for every patient, including the severity of their condition and need for treatment, and the fact that every antidepressant contains similar potential risks arising from the discontinuation of antidepressants like Cymbalta, which is stated in Cymbalta's U.S. label, and it is therefore denied.

**REQUEST FOR ADMISSION NO. 8:**

Admit that the gradual or sudden discontinuation of CYMBALTA can cause nausea.

**RESPONSE TO REQUEST FOR ADMISSION NO. 8:**

Subject to Lilly's Objections to Plaintiff's Amended Requests for Admissions, Lilly admits that in some patients who are treated with Cymbalta, the gradual or sudden discontinuation of Cymbalta is associated with nausea, as stated in Cymbalta's U.S. label, although the rate of nausea as observed in the initial short-term clinical trials was low, approximately 5.9 percent as reported in the Perahia article.

**REQUEST FOR ADMISSION NO. 9:**

Admit that the gradual or sudden discontinuation of CYMBALTA can cause headaches.

**RESPONSE TO REQUEST FOR ADMISSION NO. 9:**



Subject to Lilly's Objections to Plaintiff's Amended Requests for Admissions, Lilly admits that in some patients who are treated with Cymbalta, the gradual or sudden discontinuation of Cymbalta is associated with headaches, as stated in Cymbalta's U.S. label, although the rate of headaches as observed in the initial short-term clinical trials was low, approximately 5.3 percent as reported in the Perahia article.

**REQUEST FOR ADMISSION NO. 10:**

Admit that the gradual or sudden discontinuation of CYMBALTA can cause paresthesia.

**RESPONSE TO REQUEST FOR ADMISSION NO. 10:**

Subject to Lilly's Objections to Plaintiff's Amended Requests for Admissions, Lilly admits that in some patients who are treated with Cymbalta, the gradual or sudden discontinuation of Cymbalta is associated paresthesia, as stated in Cymbalta's U.S. label, although the rate of paresthesia as observed in the initial short-term clinical trials was low, approximately 2.9 percent as reported in the Perahia article.

**REQUEST FOR ADMISSION NO. 11:**

Admit that the gradual or sudden discontinuation of CYMBALTA can cause nightmares.

**RESPONSE TO REQUEST FOR ADMISSION NO. 11:**

Subject to Lilly's Objections to Plaintiff's Amended Requests for Admissions, Lilly admits that in some patients who are treated with Cymbalta, the gradual or sudden discontinuation of Cymbalta is associated with nightmares, as stated in Cymbalta's U.S. label that was in use between 2004 and 2010, although the rate of nightmares as observed in the initial short-term clinical trials was low, approximately 2.0 percent as reported in the Perahia article.

**REQUEST FOR ADMISSION NO. 12:**

Admit that the gradual or sudden discontinuation of CYMBALTA can cause insomnia.

**RESPONSE TO REQUEST FOR ADMISSION NO. 12:**

Subject to Lilly's Objections to Plaintiff's Amended Requests for Admissions, Lilly admits that in some patients who are treated with Cymbalta, the gradual or sudden discontinuation of Cymbalta is associated with insomnia, as stated in Cymbalta's U.S. label beginning in 2007, although the rate of insomnia as observed in the initial short-term clinical trials was low, approximately 2.0 percent as reported in the Perahia article.

**REQUEST FOR ADMISSION NO. 13:**

Admit that the gradual or sudden discontinuation of CYMBALTA can cause anxiety.

**RESPONSE TO REQUEST FOR ADMISSION NO. 13:**

Subject to Lilly's Objections to Plaintiff's Amended Requests for Admissions, Lilly admits that in some patients who are treated with Cymbalta, the gradual or sudden discontinuation of Cymbalta is associated with anxiety, as stated in Cymbalta's U.S. label, although the rate of anxiety as observed in the initial short-term clinical trials was low, below 2.0 percent as reported in the Perahia article.

**REQUEST FOR ADMISSION NO. 14:**

Admit that the gradual or sudden discontinuation of CYMBALTA can cause hyperhidrosis.

**RESPONSE TO REQUEST FOR ADMISSION NO. 14:**

Subject to Lilly's Objections to Plaintiff's Amended Requests for Admissions, Lilly admits that in some patients who are treated with Cymbalta, the gradual or sudden discontinuation of Cymbalta is associated with hyperhidrosis, as stated in Cymbalta's U.S. label, although the rate of hyperhidrosis as observed in the initial short-term clinical trials was low, below 2.0 percent as reported in the Perahia article.

**REQUEST FOR ADMISSION NO. 15:**

Admit that the gradual or sudden discontinuation of CYMBALTA can cause sensory disturbances.

**RESPONSE TO REQUEST FOR ADMISSION NO. 15:**

Subject to Lilly's Objections to Plaintiff's Amended Requests for Admissions, Lilly admits that in some patients who are treated with Cymbalta, the gradual or sudden discontinuation of Cymbalta is associated with sensory disturbances, as stated in Cymbalta's U.S. label, although the rate of sensory disturbances as observed in the initial short-term clinical trials was low, below 2.0 percent as reported in the Perahia article.

**REQUEST FOR ADMISSION NO. 16:**

Admit that the gradual or sudden discontinuation of CYMBALTA can cause suicidal ideation.

**RESPONSE TO REQUEST FOR ADMISSION NO. 16:**

Subject to Lilly's Objections to Plaintiff's Amended Requests for Admissions, Lilly responds that it lacks information sufficient to admit this Request, and it is therefore denied. Lilly admits that there had been long-standing concern in the medical community that

antidepressants may have a role in inducing suicidal ideation in certain patients, but a causal relationship has not been established. Studies have not shown an increased risk of suicidal ideation or behaviors in most adult patients treated with Cymbalta compared to those treated with placebo. However, studies show a potential, but not statistically significant, increased risk among young adults (age 18-24). Nevertheless, Cymbalta's U.S. labels warns that "patients being treated with antidepressants should be observed closely for clinical worsening and suicidality, especially at the beginning of a course of drug therapy, or at the time of dose changes, either increases or decreases."

**REQUEST FOR ADMISSION NO. 17:**

Admit that the gradual or sudden discontinuation of CYMBALTA can cause seizures.

**RESPONSE TO REQUEST FOR ADMISSION NO. 17:**

Subject to Lilly's Objections to Plaintiff's Amended Requests for Admissions, Lilly admits that there have been postmarketing reports of cases of seizure or seizure-like symptoms after discontinuation of treatment with Cymbalta and other SSRIs or SNRIs, as warned in sections of Cymbalta's U.S. label quoted in Lilly's Response to Request No. 1 and in Section 6.12 (Postmarketing Spontaneous Reports) added to the label in December 2008, but otherwise denied.

**REQUEST FOR ADMISSION NO. 18:**

Admit that, between 2004 and 2011, LILLY obtained over \$17 billion in revenue from the sale of CYMBALTA within the United States.

**RESPONSE TO REQUEST FOR ADMISSION NO. 18:**

Denied. See <https://investor.lilly.com/annuals.cfm> for information about annual revenue from the sale of Cymbalta in the United States.

**REQUEST FOR ADMISSION NO. 19:**

Admit that CYMBALTA has a shorter half-life than Prozac.

**RESPONSE TO REQUEST FOR ADMISSION NO. 19:**

Admitted.

**REQUEST FOR ADMISSION NO. 20:**

Admit that CYMBALTA has a shorter half-life than Paxil.

**RESPONSE TO REQUEST FOR ADMISSION NO. 20:**

Admitted.

**REQUEST FOR ADMISSION NO. 21:**

Admit that CYMBALTA has a shorter half-life than Zoloft.

**RESPONSE TO REQUEST FOR ADMISSION NO. 21:**

Admitted.

**REQUEST FOR ADMISSION NO. 22:**

Admit that CYMBALTA has a shorter half-life than Celexa.

**RESPONSE TO REQUEST FOR ADMISSION NO. 22:**

Admitted.

**REQUEST FOR ADMISSION NO. 23:**

Admit that CYMBALTA has a shorter half-life than Lexapro.

**RESPONSE TO REQUEST FOR ADMISSION NO. 23:**

Admitted.

**REQUEST FOR ADMISSION NO. 24:**

Admit that Effexor has a shorter half-life than CYMBALTA.

**RESPONSE TO REQUEST FOR ADMISSION NO. 24:**

Admitted.

**REQUEST FOR ADMISSION NO. 25:**

Admit that the shorter the half-life of an SSRI or SNRI, the more frequent the occurrences of WITHDRAWAL.

**RESPONSE TO REQUEST FOR ADMISSION NO. 25:**

Subject to Lilly's Objections to Plaintiff's Amended Requests for Admissions, Lilly admits that there is a relationship between the half-life of an SSRI or SNRI and discontinuation symptoms, in which a shorter half-life is one factor in the likelihood of the appearance of discontinuation-emergent adverse events ("DEAEs"), but that half-life does not explain the entire scientific picture.

**REQUEST FOR ADMISSION NO. 26:**

Admit that Daniel Kajdasz was an employee of LILLY when the PERAHIA ARTICLE was published.

**RESPONSE TO REQUEST FOR ADMISSION NO. 26:**

Admitted.

**REQUEST FOR ADMISSION NO. 27:**

Admit that Durisala Desaiiah was an employee of LILLY when the PERAHIA ARTICLE was published.

**RESPONSE TO REQUEST FOR ADMISSION NO. 27:**

Admitted.

**REQUEST FOR ADMISSION NO. 28:**

Admit that Peter Haddad has received payments from LILLY for attending advisory boards, lecturing, and consultancy work.

**RESPONSE TO REQUEST FOR ADMISSION NO. 28:**

Admitted.

**REQUEST FOR ADMISSION NO. 29:**

Admit that YOU never instructed YOUR sales force to distribute the PERAHIA ARTICLE to physicians when it was published in 2005.

**RESPONSE TO REQUEST FOR ADMISSION NO. 29:**

Lilly is still investigating the nature and extent that the sales force distributed information reflected in the PERAHIA ARTICLE, or the article itself, and thus cannot answer this request at this time.

**REQUEST FOR ADMISSION NO. 30:**

Admit that, in the six acute treatment placebo controlled trials identified in the PERAHIA ARTICLE, 44.3% of patients receiving CYMBALTA reported at least one discontinuation-emergent adverse event.

**RESPONSE TO REQUEST FOR ADMISSION NO. 30:**

Subject to Lilly's Objections to Plaintiff's Amended Requests for Admissions, Lilly admits that in the six acute treatment clinical trials discussed in the PERAHIA ARTICLE, 44.3% of patients receiving Cymbalta reported at least one discontinuation-emergent adverse event following abrupt discontinuation and 22.9% of patients receiving placebo reported at least one discontinuation-emergent adverse event.

**REQUEST FOR ADMISSION NO. 31:**

Admit that, in the six acute treatment placebo controlled trials identified in the PERAHIA ARTICLE, of the 510 discontinuation-emergent adverse events reported, 50.6% were moderate and 9.6% were severe.

**RESPONSE TO REQUEST FOR ADMISSION NO. 31:**

Subject to Lilly's Objections to Plaintiff's Amended Requests for Admissions, Lilly admits that in the six acute treatment clinical trials discussed in the PERAHIA ARTICLE, of the 510 discontinuation-emergent adverse events reported following abrupt discontinuation from Cymbalta, 39.8% were mild, 50.6% were moderate, and 9.6% were characterized as severe.



**REQUEST FOR ADMISSION NO. 32:**

Admit that, in the six acute treatment placebo controlled trials identified in the PERAHIA ARTICLE, 3.1% of patients in the CYMBALTA treatment groups withdrew from the studies because of a discontinuation-emergent adverse event.

**RESPONSE TO REQUEST FOR ADMISSION NO. 32:**

Subject to Lilly's Objections to Plaintiff's Amended Requests for Admissions, Lilly admits that in the six acute treatment clinical trials discussed in the PERAHIA ARTICLE, 3.1% of patients in the Cymbalta treatment groups withdrew from the study due to one or more discontinuation-emergent adverse events following abrupt discontinuation.

**REQUEST FOR ADMISSION NO. 33:**

Admit that, in the six acute treatment placebo controlled trials identified in the PERAHIA ARTICLE, 62.1% of patients taking 120 mg/day of CYMBALTA experienced at least one discontinuation-emergent adverse event.

**RESPONSE TO REQUEST FOR ADMISSION NO. 33:**

Subject to Lilly's Objections to Plaintiff's Amended Requests for Admissions, Lilly admits that in the six acute treatment clinical trials discussed in the PERAHIA ARTICLE, 62.1% of patients receiving 120 mg/day of Cymbalta and 22.9% of patients receiving placebo reported at least one discontinuation-emergent adverse event following abrupt discontinuation.

**REQUEST FOR ADMISSION NO. 34:**

Admit that, in the six acute treatment placebo controlled trials identified in the PERAHIA ARTICLE, of the discontinuation-emergent adverse events reported, 53.7% remained unresolved after two weeks.

**RESPONSE TO REQUEST FOR ADMISSION NO. 34:**

Subject to Lilly's Objections to Plaintiff's Amended Requests for Admissions, Lilly admits that in the six acute treatment clinical trials discussed in the PERAHIA ARTICLE, 53.7% of discontinuation-emergent adverse events reported by patients receiving Cymbalta were unresolved after two weeks and 52.5% of discontinuation-emergent adverse events reported by patients receiving placebo were unresolved after two weeks when the study concluded, but that the patients continued to remain under the care of their medical providers following the study.

**REQUEST FOR ADMISSION NO. 35:**

Admit that, in a fifty-two week open-label clinical trial for CYMBALTA identified in the PERAHIA ARTICLE, 50.8% of patients suffered at least one discontinuation-emergent adverse event.

**RESPONSE TO REQUEST FOR ADMISSION NO. 35:**

Subject to Lilly's Objections to Plaintiff's Amended Requests for Admissions, Lilly admits that in the 52-week open-label clinical trial discussed in the PERAHIA ARTICLE, 50.8% of patients receiving Cymbalta reported at least one discontinuation-emergent adverse event following abrupt discontinuation.

**REQUEST FOR ADMISSION NO. 36:**

Admit that, in a fifty-two week open-label clinical trial for CYMBALTA identified in the PERAHIA ARTICLE, of the discontinuation-emergent adverse events reported, 46.3% were moderate and 17.2% were severe.

**RESPONSE TO REQUEST FOR ADMISSION NO. 36:**

Subject to Lilly's Objections to Plaintiff's Amended Requests for Admissions, Lilly admits that in the 52-week open-label clinical trial discussed in the PERAHIA ARTICLE, of the discontinuation-emergent adverse events reported following abrupt discontinuation, 36.6% were mild, 46.3% were moderate, and 17.2% were characterized as severe.

**REQUEST FOR ADMISSION NO. 37:**

Admit that, in a fifty-two week open-label clinical trial for CYMBALTA identified in the PERAHIA ARTICLE, of the discontinuation-emergent adverse events reported 55.2% had not resolved after two weeks.

**RESPONSE TO REQUEST FOR ADMISSION NO. 37:**

Subject to Lilly's Objections to Plaintiff's Amended Requests for Admissions, Lilly admits that in the 52-week open-label clinical trial discussed in the PERAHIA ARTICLE, of the discontinuation-emergent adverse events reported, 55.2% had not resolved after two weeks when the study concluded, but that the patients continued to remain under the care of their medical providers following the study.

**REQUEST FOR ADMISSION NO. 38:**

Admit that LILLY does not know how long it took for the discontinuation-emergent adverse events discussed in the PERAHIA ARTICLE to fully resolve.

**RESPONSE TO REQUEST FOR ADMISSION NO. 38:**

Denied in part. Lilly admits it knows that of the discontinuation-emergent adverse events reported in the six acute treatment clinical trials discussed in the PERAHIA ARTICLE, 46.3% of those reported by patients receiving Cymbalta and 47.5% of those reported by patients on

placebo resolved within two weeks. Lilly further admits it knows that of the discontinuation-emergent adverse events reported in the two long-term treatment clinical trials discussed in the PERAHIA ARTICLE, 35.3% of those reported by patients receiving Cymbalta resolved within two weeks and 50% of those reported by patients on placebo resolved within one week. Lilly further admits it knows that of the discontinuation-emergent adverse events reported in the 52-week open-label clinical trial discussed in the PERAHIA ARTICLE, 44.8% of those reported resolved within two weeks. Because the trials concluded after the end of two weeks post-discontinuation, the trials did not capture this information from the medical professionals who continued to treat the patients at the conclusion of the trials.

**REQUEST FOR ADMISSION NO. 39:**

Admit that the work conducted in the PERAHIA ARTICLE was funded by LILLY.

**RESPONSE TO REQUEST FOR ADMISSION NO. 39:**

Admitted.

**REQUEST FOR ADMISSION NO. 40:**

Admit that the DEAEs measured in the PERAHIA ARTICLE were assessed by means of spontaneous reports rather than a symptom checklist.

**RESPONSE TO REQUEST FOR ADMISSION NO. 40:**

Subject to Lilly's Objections to Plaintiff's Amended Requests for Admissions, Lilly admits that in the trials discussed in the PERAHIA ARTICLE, DEAEs were assessed by means of an open-ended question posed to patients to solicit information about their adverse symptoms and not by means of a symptom checklist in which patients are asked about each specific symptom.

**REQUEST FOR ADMISSION NO. 41:**

Admit that use of a symptom checklist, instead of spontaneous reports, would be expected to produce higher incidence rates of DEAEs in the PERAHIA ARTICLE.

**RESPONSE TO REQUEST FOR ADMISSION NO. 41:**

Subject to Lilly's Objections to Plaintiff's Amended Requests for Admissions, Lilly admits that the use of a symptom checklist to measure DEAEs might be expected to produce higher reporting rates of DEAEs for both active treatment and placebo than alternate means of assessment in part due to the suggestive influence of a symptom checklist on patients.

**REQUEST FOR ADMISSION NO. 42:**

Admit that LILLY sponsored the clinical trial by Jerrold Rosenbaum et al, Selective Serotonin Reuptake Inhibitor Discontinuation Syndrome: A Randomized Clinical Trial, 44 BIOLOGICAL PSYCHIATRY 2, 77-87 (1998).

**RESPONSE TO REQUEST FOR ADMISSION NO. 42:**

Admitted.

**REQUEST FOR ADMISSION NO. 43:**

Admit that, in Jerrold Rosenbaum et al, Selective Serotonin Reuptake Inhibitor Discontinuation Syndrome: A Randomized Clinical Trial, 44 BIOLOGICAL PSYCHIATRY 2, 77-87 (1998), the researchers used a symptom checklist to tabulate DEAEs / withdrawal symptoms.

**RESPONSE TO REQUEST FOR ADMISSION NO. 43:**

Admitted.

**REQUEST FOR ADMISSION NO. 44:**

Admit that the information contained in the European Medicines Agency Summary of Product Information for CYMBALTA is accurate and true.

**RESPONSE TO REQUEST FOR ADMISSION NO. 44:**

Admitted subject to Lilly's Objections to Plaintiff's Amended Requests for Admissions.

**REQUEST FOR ADMISSION NO. 45:**

Admit that, in clinical trials, adverse events seen on abrupt treatment discontinuation of CYMBALTA occurred in approximately 45% of patients treated with CYMBALTA.

**RESPONSE TO REQUEST FOR ADMISSION NO. 45:**

Denied in part. Lilly admits that in some clinical trials, specifically the six acute treatment clinical trials discussed in the PERAHIA ARTICLE, discontinuation-emergent adverse events after abrupt discontinuation were reported by 44.3% of patients on active treatment and 22.9% on placebo. In other clinical trials, the incidence of DEAEs was a different rate. For example, in the two long-term treatment clinical trials discussed in the PERAHIA ARTICLE, discontinuation-emergent adverse events after abrupt discontinuation were reported by 9.1% of patients.

**REQUEST FOR ADMISSION NO. 46:**

Admit that the following statement appears in the European Medicines Agency Summary of Product Information for CYMBALTA: "In clinical trials adverse events seen on abrupt treatment discontinuation occurred in approximately 45% of patients treated with Cymbalta and 23% of patients taking placebo."

**RESPONSE TO REQUEST FOR ADMISSION NO. 46:**

Admitted.

**REQUEST FOR ADMISSION NO. 47:**

Admit that the following statement does not appear on the CYMBALTA LABEL: “In clinical trials adverse events seen on abrupt treatment discontinuation occurred in approximately 45% of patients treated with Cymbalta and 23% of patients taking placebo.”

**RESPONSE TO REQUEST FOR ADMISSION NO. 47:**

Denied. The above-quoted statement appears in the CYMBALTA LABEL as defined by Plaintiff as “the official prescribing information for the drug, including but not limited to the product insert and medication guides approved by the FDA or other foreign regulatory bodies.”

**REQUEST FOR ADMISSION NO. 48:**

Admit that at no time has LILLY’s direct-to-consumer advertising, i.e., television, newspapers, magazines, and/or radio, warned patients that abrupt discontinuation of CYMBALTA occurred in approximately 45% of patients treated with CYMBALTA.

**RESPONSE TO REQUEST FOR ADMISSION NO. 48:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR ADMISSION NO. 49:**

Admit that the following statement appears in the European Medicines Agency Summary of Product Information for CYMBALTA: “It is therefore advised that duloxetine should be gradually tapered when discontinuing treatment over a period of no less than 2 weeks, according to the patient’s needs (see section 4.2).”

**RESPONSE TO REQUEST FOR ADMISSION NO. 49:**

Admitted.

**REQUEST FOR ADMISSION NO. 50:**

Admit that the CYMBALTA LABEL does not state that CYMBALTA should be gradually tapered “over a period of no less than 2 weeks[.]”

**RESPONSE TO REQUEST FOR ADMISSION NO. 50:**

Denied. The above-quoted statement appears in the CYMBALTA LABEL as defined by Plaintiff as “the official prescribing information for the drug, including but not limited to the product insert and medication guides approved by the FDA or other foreign regulatory bodies.”

**REQUEST FOR ADMISSION NO. 51:**

Admit that the European Medicines Agency Summary of Product Information for CYMBALTA refers to “discontinuation-emergent adverse events” as “withdrawal symptoms.”

**RESPONSE TO REQUEST FOR ADMISSION NO. 51:**

Admitted.

**REQUEST FOR ADMISSION NO. 52:**

Admit that the following statement appears in the European Medicines Agency Summary of Product Information for CYMBALTA: Withdrawal symptoms “may be prolonged (2-3 months or more).”

**RESPONSE TO REQUEST FOR ADMISSION NO. 52:**

Lilly admits that Cymbalta’s European Medicines Agency Summary of Product Characteristics states, concerning discontinuation-emergent adverse events: “Generally these



symptoms are self-limiting and usually resolve within 2 weeks, though in some individuals they may be prolonged (2-3 months or more).”

**REQUEST FOR ADMISSION NO. 53:**

Admit that the CYMBALTA LABEL does not estimate how long discontinuation-emergent adverse events will likely take to resolve following abrupt or tapered discontinuation of CYMBALTA.

**RESPONSE TO REQUEST FOR ADMISSION NO. 53:**

Denied. An estimate of the duration of discontinuation-emergent adverse events appears in the CYMBALTA LABEL as defined by Plaintiff as “the official prescribing information for the drug, including but not limited to the product insert and medication guides approved by the FDA or other foreign regulatory bodies.”

**REQUEST FOR ADMISSION NO. 54:**

Admit that the CYMBALTA LABEL does not indicate that some individuals may have withdrawal symptoms for 2-3 months or more.

**RESPONSE TO REQUEST FOR ADMISSION NO. 54:**

Denied. A statement that some individuals may experience prolonged discontinuation-emergent adverse events for 2-3 months or more appears in the CYMBALTA LABEL as defined by Plaintiff as “the official prescribing information for the drug, including but not limited to the product insert and medication guides approved by the FDA or other foreign regulatory bodies.”

**REQUEST FOR ADMISSION NO. 55:**

Admit that the CYMBALTA LABEL does not specify what percentage of patients will likely experience at least one discontinuation-emergent adverse event upon abrupt or tapered discontinuation of CYMBALTA.

**RESPONSE TO REQUEST FOR ADMISSION NO. 55:**

Denied. A statement of the percentage of patients who reported discontinuation-emergent adverse events in clinical trials appears in the CYMBALTA LABEL as defined by Plaintiff as “the official prescribing information for the drug, including but not limited to the product insert and medication guides approved by the FDA or other foreign regulatory bodies.”

**REQUEST FOR ADMISSION NO. 56:**

Admit that YOU, not the FDA, bear responsibility for the content of the CYMBALTA LABEL at all times.

**RESPONSE TO REQUEST FOR ADMISSION NO. 56:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR ADMISSION NO. 57:**

Admit that the smallest approved dose for CYMBALTA is 20 mg.

**RESPONSE TO REQUEST FOR ADMISSION NO. 57:**

Admitted.

**REQUEST FOR ADMISSION NO. 58:**

Admit that CYMBALTA has an elimination half-life of about 12 hours (range 8 to 17 hours).

**RESPONSE TO REQUEST FOR ADMISSION NO. 58:**

Admitted.

**REQUEST FOR ADMISSION NO. 59:**

Admit that CYMBALTA should be swallowed whole and should not be chewed or crushed.

**RESPONSE TO REQUEST FOR ADMISSION NO. 59:**

Admitted.

**REQUEST FOR ADMISSION NO. 60:**

Admit that the CYMBALTA capsule should not be opened and its contents sprinkled on food or mixed with liquids.

**RESPONSE TO REQUEST FOR ADMISSION NO. 60:**

Admitted.

**REQUEST FOR ADMISSION NO. 61:**

Admit that opening a CYMBALTA capsule, or crushing or chewing the CYMBALTA capsule, might affect its enteric coating.

**RESPONSE TO REQUEST FOR ADMISSION NO. 61:**

Admitted.

Respectfully Submitted,

Dated: March 9, 2015

By: \_\_\_\_\_/s/  
Jeffrey T. Bozman (83679)  
Covington & Burling LLP  
One CityCenter  
850 Tenth Street, NW  
Washington, DC 20001  
Tel: (202) 662-5829  
Fax: (202) 778-5829  
*Counsel for Eli Lilly and Company*

**CERTIFICATE OF SERVICE**

I, Jeffrey T. Bozman, hereby certify that on the 9th day of March, 2015, I have served Plaintiff's counsel in this action with a copy of Defendant's Responses to Plaintiff's First Set of Requests for Admission by mailing a copy of the same by United States Mail, postage prepaid, and electronic mail to the following address:

Peter A. Miller  
**Miller Legal LLC**  
175 S. Pantops Drive, Third Floor  
Charlottesville, VA 2291  
Telephone (434) 529-6909  
Facsimile (888) 830-1488  
PMiller@MillerLegalLLC.com  
*Counsel for Janine Ali*

Dated: March 9, 2015

By:                     /s/                      
Jeffrey T. Bozman (83679)  
Covington & Burling LLP  
One CityCenter  
850 Tenth Street, NW  
Washington, DC 20001  
Tel: (202) 662-5829  
Fax: (202) 778-5829  
*Counsel for Eli Lilly and Company*

## Exhibit 3-A

**UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF VIRGINIA  
ALEXANDRIA DIVISION**

JANINE ALI,

Plaintiff,

v.

ELI LILLY AND COMPANY, an Indiana  
corporation,

Defendant.

**CASE NO. 1:14-CV-01615-GBL-TRJ**

**PLAINTIFF'S FIRST SET OF INTERROGATORIES TO DEFENDANT**

**PROPOUNDING PARTY:** Plaintiff, Janine Ali

**RESPONDING PARTY:** Defendant Eli Lilly and Company

**SET NO.:** ONE

Plaintiff Janine Ali ("PLAINTIFF"), by and through her attorneys, and pursuant to Federal Rule of Civil Procedure 26 and 33, does hereby serve written requests upon Defendant Eli Lilly and Company, ("LILLY") to answer the following interrogatories in writing, under oath, and in accordance with the following definitions and instructions, within thirty (30) days of service.

**DEFINITIONS**

The following definitions apply to each request below and are incorporated therein:

1. "ALL" means "any and all" and the word "any" means "any and all."
2. The term "CYMBALTA" means duloxetine hydrochloride, including any other name or trademark under which it is sold, domestically *or* abroad, marketed or produced, including products sold, marketed, or produced by others if they do so with your permission, at

your request, at your direction, with your acquiescence, and/or if you gain any benefit from their sales, marketing, or distribution.

3. The term “COMMUNICATION” means and refers to every method and manner of transmitting or receiving data, opinions, thoughts, inquiries, representations and other information, whether orally, in writing, electronically, or otherwise, between two or more persons or entities. Communications include drafts and other written information intended for communicating to another person, even if not ultimately transmitted to or received by another person.

4. The term “IDENTIFY” (in reference to a person) means to state, to the extent known, the person’s full name, present or last known address, telephone number, company title (to the extent applicable), and whether or not the person is currently an employee of LILLY (to the extent applicable).

5. The terms “CONCERNING,” “RELATING,” and/or “REGARDING” mean containing, alluding to, responding to, commenting upon, discussing, explaining, mentioning, analyzing, constituting, memorializing, comprising, repeating, incorporating, confirming, listing, evidencing, setting forth, summarizing, or characterizing, either directly or indirectly, in whole or in part.

6. The term “DEAE” means Discontinuation Emergent Adverse Event, and refers to any possible side effects or symptoms relating to discontinuing, withdrawing, or tapering from the use, consumption, or treatment with Cymbalta.

7. The term “WITHDRAWAL” includes discontinuation or tapering, as well as DEAEs, withdrawal symptoms, and any side effects of withdrawing, discontinuing, or tapering from CYMBALTA.



8. The term “DOCUMENT” shall have the broadest meaning possible under Rule 34 of the Federal Rules of Civil Procedure and includes all originals and drafts, in any and all languages, of any nature whatsoever, in your possession, custody or control, regardless of where located, and include, but are not limited to, letters, correspondence, logs, drafts, contracts, prospective contracts, agreements, reports, records, studies, surveys, resolutions, tabulations, notes, summaries, memoranda, Electronically Stored Information (“ESI”), electronic mail (“email”), calendar or diary entries, handwritten notes, working papers, work sheets, spread sheets, diagrams, minutes of meetings, agendas, bulletins, periodicals, circulars, advertisements, notices, announcements, invoices, statements, checks (front and back), bank statements, ledgers, orders, vouchers, instructions, drawings, charts, graphs, manuals, brochures, pamphlets, schedules, telegrams, teletypes, photographs, audio tapes, voice-mail messages, videotapes, electronic recordings, facsimile transmissions, and information of whatever kind either stored on computers, including computer disks, hard drives and other media, or contained in any computer or information retrieval devices.

9. The terms “ELI LILLY,” “LILLY,” “YOU” or “YOUR” refer to Eli LILLY and Company, its respective officers, directors, employees, representatives, subsidiaries, and affiliates thereof, as well as all persons acting for, on behalf of, or in concert with Eli LILLY and Company’s behalf, including agents, attorneys, accountants, and investigators.

10. The term “FDA” means the United States Food & Drug Administration.

11. The term “INCLUDING” means “including, but not limited to.”

12. The term “LABEL” refers to the official prescribing information for the drug, including but not limited to the product insert and medication guides approved by the FDA or other foreign regulatory bodies.

13. The term “MEDICAL PROFESSIONAL” includes healthcare providers, prescribing doctors, non-prescribing doctors, physicians, pharmacists, nurses, and other individuals who provide healthcare services.

14. The term “PERAHIA ARTICLE” refers to David G. Perahia, *et al.*, *Symptoms Following Abrupt Discontinuation of Duloxetine Treatment in Patients with Major Depressive Disorder*, 89 J. Affective Disorders 207-12 (2005).

15. The term “SNRI” means serotonin norepinephrine reuptake inhibitor.

16. The term “SSRI” means selective serotonin reuptake inhibitor.

17. The use of the terms “or,” “and,” and “and/or” should be construed conjunctively and disjunctively for the broadest possible meaning.

18. The term “person” or “people” includes individuals, corporations, partnerships, associations, and other bodies and entities, as well as their representatives, agents, employees and attorneys.

19. The terms “research,” “study,” or “analysis,” when used as a noun mean and refer to any research, analysis, study, report, evaluation or assessment. The term research when used as a verb means to research, analyze, study, report, evaluate, or assess.

20. The term “use” means to “employ something for a purpose,” “to do something habitually,” “to consume something,” “to manipulate,” “to benefit from,” as well as to allow others to “use,” or acquiesce in others’ “use.”

21. The singular use of any term or phrase includes its plural, and the plural of any term or phrase includes its singular.

22. The use of any tense of any verb shall also include within its meaning all other tenses of that verb.

## **INTERROGATORIES**

### **INTERROGATORY NO. 1:**

Please IDENTIFY all current and former employees or consultants who were involved in drafting, editing, creating, and submitting to the FDA, the sections of the US CYMBALTA LABEL titled “Discontinuation of Treatment with Cymbalta,” and/or “Dosage and Administration” or “Medication Administration” or “Information for Patients” (depending on year).

### **INTERROGATORY NO. 2:**

Please IDENTIFY all LILLY current and former employees who worked on CYMBALTA in the following department/divisions/sections of LILLY:

- Global Scientific Communications and Information
- Regulatory Affairs
- The LILLY Answer Center
- US Brand Cymbalta Team
- Global Labeling Department
- Discovery and Early phase teams
- Global Medical Affairs
- Global Patient Safety
- Global/Product Development
- Neuroscience Strategy Group
- Any CYMBALTA-specific committee, team, or group

### **INTERROGATORY NO. 3:**

For each category below, please IDENTIFY ten (10) current or former employees or consultants who are knowledgeable, at least in part, on the following topics. If an individual only has knowledge of a subpart of one of these topics, please explain:

- The marketing and advertising of CYMBALTA to MEDICAL PROFESSIONALS
- The marketing and advertising of CYMBALTA to consumers
- The drafting, editing, creating, and submitting to the FDA of the US CYMBALTA LABEL, with specific reference to the sections of the label titled “Discontinuation of Treatment with Cymbalta,” “Dosage and Administration” or “Medication Administration” or “Information for Patients” (depending on year).
- The drafting, editing, creating, and submitting to the European Medicines Agency of

the CYMBALTA LABEL, with specific reference to the sections of the label concerning WITHDRAWAL.

- CYMBALTA WITHDRAWAL
- Clinical trials related to CYMBALTA and WITHDRAWAL
- Domestic regulatory issues related to CYMBALTA
- Foreign regulatory issues related to CYMBALTA
- Educational programs for CYMBALTA
- Training of sales representatives relative to CYMBALTA

**INTERROGATORY NO. 4:**

Please IDENTIFY all non-employee medical doctors retained, paid, or compensated in any way (directly or indirectly), by or on behalf of LILLY to present materials and information about CYMBALTA to other doctors, including but not limited to Key Opinion Leaders (KOLs), Thought Leaders and doctors on LILLY's Speaker's Bureau.

**INTERROGATORY NO. 5:**

Please list, by year, the total amount of payments, including but not limited to any compensation, gifts, payments, honoraria, or consulting fees, made to those individuals identified in Interrogatory No. 4.

**INTERROGATORY NO. 6:**

Please IDENTIFY all third-party vendors used by LILLY to organize, create, and/or conduct for education programs wherein CYMBALTA was discussed.

**INTERROGATORY NO. 7:**

Please IDENTIFY all third-parties that LILLY consulted with and/or hired to engage in direct-to-consumer advertising for CYMBALTA.

**INTERROGATORY NO. 8:**

Please IDENTIFY all third-parties that LILLY consulted with and/or hired to plan and/or publish medical journal articles related to CYMBALTA.

**INTERROGATORY NO. 9:**

Please IDENTIFY all third-parties that LILLY consulted with and/or hired to engage in

public relations related to CYMBALTA.

**INTERROGATORY NO. 10:**

Please IDENTIFY all sales representatives employed by LILLY or by a third-party contracted by LILLY to provide information to MEDICAL PROFESSIONALS healthcare providers concerning CYMBALTA who visited the following:

- Dr. Navera R. Ahmad  
Virginia Hospital Center  
1701 N. George Mason Drive  
Arlington, VA 22205  
(703) 525-3069
- Dr. Thonia Hafez Gab-Allah (retired)  
(571) 232-1309
- Dr. Jayasree Patla  
Alexandria Healthcare  
6303 Little River Turnpike, Suite 160  
Alexandria, VA 22312  
(703) 658-2650

**INTERROGATORY NO. 11:**

Please list, by year, the total amount of payments, including but not limited to any compensation, gifts, payments, honoraria, or consulting fees, made to:

- Dr. Navera R. Ahmad  
Virginia Hospital Center  
1701 N. George Mason Drive  
Arlington, VA 22205  
(703) 525-3069
- Dr. Thonia Hafez Gab-Allah (retired)  
(571) 232-1309
- Dr. Jayasree Patla  
Alexandria Healthcare  
6303 Little River Turnpike, Suite 160  
Alexandria, VA 22312  
(703) 658-2650

**INTERROGATORY NO. 12:**

Please list the title, date, duration, and location of any LILLY-sponsored education program that discussed CYMBALTA, attended by any of the following, divided by individual:

- Dr. Navera R. Ahmad  
Virginia Hospital Center  
1701 N. George Mason Drive  
Arlington, VA 22205  
(703) 525-3069
- Dr. Thonia Hafez Gab-Allah (retired)  
(571) 232-1309
- Dr. Jayasree Patla  
Alexandria Healthcare  
6303 Little River Turnpike, Suite 160  
Alexandria, VA 22312  
(703) 658-2650

**INTERROGATORY NO. 13:**

Please explain, to the best of LILLY's knowledge, why adverse reactions sometimes occur upon the discontinuation of CYMBALTA treatment.

**INTERROGATORY NO. 14:**

Please explain LILLY's reason for changing the US LABEL concerning "Discontinuation of Treatment with Cymbalta" in 2008 from "the following symptoms occurred at a rate greater than or equal to 2%" to "the following symptoms occurred at a rate greater than or equal to 1%."

**INTERROGATORY NO. 15:**

Please explain LILLY's reason for adding to the 2009 US CYMBALTA LABEL "or tapered" in the context of "Following abrupt ... discontinuation ..." in the section titled "Discontinuation of Treatment with Cymbalta."

**INTERROGATORY NO. 16:**

Please explain LILLY's reason for changing the US CYMBALTA LABEL in 2012 from

“the following symptoms occurred at a rate greater than or equal to 1%” to “at 1% or greater” in the section titled “Discontinuation of Treatment with Cymbalta.”

**INTERROGATORY NO. 17:**

Please explain the reason LILLY included in its labeling in European countries that adverse events seen on abrupt treatment discontinuation of CYMBALTA occurred in approximately 45% of patients treated with CYMBALTA, but did not disclose that information on the FDA-approved LABEL.

**INTERROGATORY NO. 18:**

Provide the citation of every journal publication that LILLY sponsored, paid for, or was otherwise involved in creating, that relates to WITHDRAWAL associated with SSRIs or SNRIs, including but not limited to CYMBALTA, Prozac, Zoloft, Paxil, and Effexor.

**INTERROGATORY NO. 19:**

Provide the citation of every journal publication that LILLY sponsored, paid for, or was otherwise involved in creating, that relates to CYMBALTA.

**INTERROGATORY NO. 20:**

Provide the citation of every journal publication that LILLY sponsored, paid for, or was otherwise involved in creating, that relates to the down regulation of neurotransmitters and any SSRI or SNRI, including but not limited to CYMBALTA, Prozac, Zoloft, Paxil, and Effexor.

**INTERROGATORY NO. 21:**

List every placebo-controlled, active-controlled, and open-label clinical trial involving CYMBALTA, which contained a measurement designed to measure WITHDRAWAL, indicating for each trial: the date of the trial (started and completed); the location of the trial; whether the trial was completed as part of an Investigational New Drug Application, and if so, its

designation; whether the trial was published in a medical journal, and if so, the citation; and whether the results of the trial were shared with the FDA.

**INTERROGATORY NO. 22:**

Please state the amount of revenue, by year, that LILLY obtained from the sale of CYMBALTA within the United States between its approval in 2004 and the present.

Dated: February 4, 2015

Respectfully submitted,

**MILLER LEGAL, LLC**

/s/ Brielle M. Hunt

Brielle M. Hunt  
Miller Legal, LLC  
175 South Pantops Drive, Ste. 301  
Charlottesville, Virginia 22911  
Tel: (434) 529-6909  
Fax: (800) 768-9542  
Email: [bhunt@millerlegalllc.com](mailto:bhunt@millerlegalllc.com)

-and-

**BAUM HEDLUND ARISTEI & GOLDMAN,  
P.C.**

/s/ R. Brent Wisner

Brent Wisner, Esq. (*pro hac vice*)  
12100 Wilshire Blvd., Suite 950  
Los Angeles, CA 90025  
(310) 207-3233  
(310) 207-4204 (fax)  
Email: [rbwisner@baumgedlundlaw.com](mailto:rbwisner@baumgedlundlaw.com)



**CERTIFICATE OF SERVICE**

I hereby certify that on this 4<sup>th</sup> day of February, 2015, a true and correct copy of the foregoing **PLAINTIFF'S FIRST SET OF INTERROGATORIES TO DEFENDANT** was served via Electronic Mail, upon the following:

Jeffrey Todd Bozman  
Brett C. Reynolds (pro hac vice)  
Michael X. Imbroscio (pro hac vice)  
Phyllis A. Jones (pro hac vice)  
**COVINGTON & BURLING LLP**  
One City Center  
850 Tenth Street, NW  
Washington, DC 20001  
Email: [jbozman@cov.com](mailto:jbozman@cov.com)  
Email: [breynolds@cov.com](mailto:breynolds@cov.com)  
Email: [mimbrosio@cov.com](mailto:mimbrosio@cov.com)  
Email: [pajones@cov.com](mailto:pajones@cov.com)

*Attorneys for Eli Lilly and Company*

/s/

\_\_\_\_\_  
Samantha Jison

## Exhibit 3-B

**UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF VIRGINIA  
ALEXANDRIA DIVISION**

JANINE ALI

Plaintiff,

v.

ELI LILLY AND COMPANY, an Indiana  
corporation,

Defendant.

CASE NO.: 1:14-CV-01615-GBL-TRJ

**DEFENDANT’S OBJECTIONS TO PLAINTIFF’S FIRST SET OF  
INTERROGATORIES**

Defendant Eli Lilly and Company (“Defendant” or “Lilly”) hereby submits its objections to Plaintiff’s First Set of Interrogatories, as follows:

**GENERAL STATEMENTS AND OBJECTIONS**

Lilly objects to these Interrogatories as exceeding Federal Rule of Civil Procedure 33’s limitation on the number of interrogatories that may be propounded by a party without leave of court. Lilly construes these Interrogatories as totaling forty-one (41), including all subparts. Subject to this objection, Lilly has addressed all the following interrogatories.

**OBJECTIONS TO DEFINITIONS**

1. Lilly objects to the definitions of the terms “ELI LILLY”, “LILLY”, “YOU”, and “YOUR” to the extent that they seek to extend these definitions to persons or entities other than the named Defendant in this litigation, Eli Lilly and Company, and purport to call for information or documents that are not in the possession, custody, or control of Eli Lilly and Company. For purposes of its objections and responses, Lilly will define “ELI LILLY”,

“LILLY”, “YOU”, and “YOUR” to mean Eli Lilly and Company. Lilly will limit its responses to information and documents that are in the possession, custody, or control of Eli Lilly and Company.

2. Lilly objects to the definition of “DOCUMENT” to the extent that it imposes obligations on Lilly beyond those in the Federal Rules of Civil Procedure.

### **SPECIFIC OBJECTIONS TO INTERROGATORIES**

#### **INTERROGATORY NO. 1:**

Please IDENTIFY all current and former employees or consultants who were involved in drafting, editing, creating, and submitting to the FDA, the sections of the US CYMBALTA LABEL titled “Discontinuation of Treatment with Cymbalta,” and/or “Dosage and Administration” or “Medication Administration” or “Information for Patients” (depending on year).

#### **OBJECTIONS TO INTERROGATORY NO. 1:**

Lilly objects to this Interrogatory as overly broad and unduly burdensome as to time and scope and to the use of “involved” as vague and ambiguous. Scores of Lilly employees have had some involvement in Cymbalta’s labeling over the last 10 years, and the voluminous documents that have already been provided to Plaintiff’s counsel, including the regulatory files for Cymbalta, contain extensive information about the Lilly employees and other individuals who have worked on labeling issues. Requiring Lilly to compile a list of “all” such individuals is not reasonable, especially since the identity of such individuals is now also in Plaintiff’s possession. When it responds to this Interrogatory, Lilly will make a good faith effort to identify the key employees or consultants who played a significant role in or were responsible for the creation of Cymbalta’s United States Package Insert (“U.S. label”).

**INTERROGATORY NO. 2:**

Please IDENTIFY all LILLY current and former employees who worked on CYMBALTA in the following department/divisions/sections of LILLY:

- Global Scientific Communications and Information
- Regulatory Affairs
- The LILLY Answer Center
- US Brand Cymbalta Team
- Global Labeling Department
- Discovery and Early phase teams
- Global Medical Affairs
- Global Patient Safety
- Global/Product Development
- Neuroscience Strategy Group
- Any CYMBALTA-specific committee, team, or group

**OBJECTIONS TO INTERROGATORY NO. 2:**

This Interrogatory essentially seeks a listing of every employee who has ever had any role in Cymbalta, which likely subsumes hundreds if not thousands of Lilly employees.

Compiling such a comprehensive list would be nearly impossible, and the burden of attempting to do so far outweighs any conceivable need for such information. Lilly is willing to discuss identifying certain key employees with central relevant responsibilities for Cymbalta, but Lilly cannot respond to this request as written, and therefore objects to the Interrogatory in its entirety. (Lilly also notes that this Interrogatory as written contains eleven (11) discrete subparts, each concerning a different department, division, or team within Lilly. As such, Lilly construes this as eleven separate interrogatories.)

**INTERROGATORY NO. 3:**

For each category below, please IDENTIFY ten (10) current or former employees or consultants who are knowledgeable, at least in part, on the following topics. If an individual only has knowledge of a subpart of one of these topics, please explain:

- The marketing and advertising of CYMBALTA to MEDICAL PROFESSIONALS
- The marketing and advertising of CYMBALTA to consumers
- The drafting, editing, creating, and submitting to the FDA of the US CYMBALTA LABEL, with specific reference to the sections of the label titled “Discontinuation of Treatment with Cymbalta,” “Dosage and Administration” or “Medication Administration” or “Information for Patients” (depending on year).
- The drafting, editing, creating, and submitting to the European Medicines Agency of the CYMBALTA LABEL, with specific reference to the sections of the label concerning WITHDRAWAL.
- CYMBALTA WITHDRAWAL
- Clinical trials related to CYMBALTA and WITHDRAWAL
- Domestic regulatory issues related to CYMBALTA
- Foreign regulatory issues related to CYMBALTA
- Educational programs for CYMBALTA
- Training of sales representatives relative to CYMBALTA

**OBJECTIONS TO INTERROGATORY NO. 3:**

This Interrogatory seeks a listing of 100 employees who had a broad range of roles relating to Cymbalta. Compiling such a comprehensive list would be nearly impossible, and the burden of attempting to do so far outweighs any conceivable need for information of this scope. Lilly is willing to discuss identifying certain key employees with central relevant responsibilities for Cymbalta, but Lilly cannot respond to this request as written, and therefore objects to the Interrogatory in its entirety. (Lilly also notes that this Interrogatory as written contains eleven (10) discrete subparts, each concerning a different department, division, or team within Lilly. As such, Lilly construes this as ten separate interrogatories.)

**INTERROGATORY NO. 4:**

Please IDENTIFY all non-employee medical doctors retained, paid, or compensated in any way (directly or indirectly), by or on behalf of LILLY to present materials and information about CYMBALTA to other doctors, including but not limited to Key Opinion Leaders (KOLs), Thought Leaders and doctors on LILLY's Speaker's Bureau.

**OBJECTIONS TO INTERROGATORY NO. 4:**

Lilly objects to this Interrogatory as overly broad as to time and scope. Lilly also objects to the this Interrogatory to the extent it mischaracterizes the role of Key Opinion Leaders, Thought Leaders, or any other Lilly-affiliated non-employee doctors. Lilly will be responding to this Interrogatory with information about external payments to physicians by reference to the extensive information on this subject already provided to Plaintiff's counsel.

**INTERROGATORY NO. 5:**

Please list, by year, the total amount of payments, including but not limited to any compensation, gifts, payments, honoraria, or consulting fees, made to those individuals identified in Interrogatory No. 4.

**OBJECTIONS TO INTERROGATORY NO. 5:**

Lilly objects to this Interrogatory as overly broad as to time and scope. As noted above, Lilly will be responding to this Interrogatory with information about external payments to physicians by reference to the extensive information on this subject already provided to Plaintiff's counsel.

**INTERROGATORY NO. 6:**

Please IDENTIFY all third-party vendors used by LILLY to organize, create, and/or conduct for education programs wherein CYMBALTA was discussed.

**OBJECTIONS TO INTERROGATORY NO. 6:**

Lilly objects to this Interrogatory as overly broad and unduly burdensome as to time and scope. To the extent that this Interrogatory seeks identification of “all third-parties,” the burden of complying with this Interrogatory outweighs Plaintiff’s need for information of this scope. As such, Lilly will identify the principal agencies retained for education programs to the extent those programs contained Cymbalta-specific information.

**INTERROGATORY NO. 7:**

Please IDENTIFY all third-parties that LILLY consulted with and/or hired to engage in direct-to-consumer advertising for CYMBALTA.

**OBJECTIONS TO INTERROGATORY NO. 7:**

Lilly objects to this Interrogatory as overly broad and unduly burdensome as to time and scope. To the extent that this Interrogatory seeks identification of “all third-parties,” the burden of complying with this Interrogatory outweighs Plaintiff’s need for information of this scope. As such, Lilly will identify the principal agencies retained for Cymbalta direct-to-consumer advertising.

**INTERROGATORY NO. 8:**

Please IDENTIFY all third-parties that LILLY consulted with and/or hired to plan and/or publish medical journal articles related to CYMBALTA.



**OBJECTIONS TO INTERROGATORY NO. 8:**

Lilly objects to this Interrogatory to the extent it implies that Lilly pays medical journals or third parties to publish Lilly-sponsored articles. Lilly also objects to this Interrogatory as overly broad as to time and scope to the extent that it seeks Lilly to identify every individual who had any involvement in the publication of any article relating to Cymbalta. Plaintiff is aware of the publications involving Cymbalta that relate to the discontinuation symptoms that are the focus of this lawsuit, the authors and associated disclosures appear on the face of those articles, and Plaintiffs have already deposed a principal author of those articles in *Hexum v. Eli Lilly & Co.*, Case No. 2:12-cv-2701-SVW (MAN) (C.D. Cal) and *Herrera v. Eli Lilly & Co.*, Case No. 2:12-cv-2702-SVW (MAN) (C.D. Cal.) (“the *Hexum/Herrera* actions”). Lilly will not be responding to this Interrogatory.

**INTERROGATORY NO. 9:**

Please IDENTIFY all third-parties that LILLY consulted with and/or hired to engage in public relations related to CYMBALTA.

**OBJECTIONS TO INTERROGATORY NO. 9:**

Lilly objects to this Interrogatory as overly broad as to time and scope. Lilly’s engagement of public relations agencies is not relevant to this matter nor likely to lead to the discovery of admissible evidence, and Lilly will not be responding to this Interrogatory.

**INTERROGATORY NO. 10:**

Please IDENTIFY all sales representatives employed by LILLY or by a third-party contracted by LILLY to provide information to MEDICAL PROFESSIONALS healthcare providers concerning CYMBALTA who visited the following:

- Dr. Navera R. Ahmad  
Virginia Hospital Center  
1701 N. George Mason Drive  
Arlington, VA 22205  
(703) 525-3069
- Dr. Thonia Hafez Gab-Allah (retired)  
(571) 232-1309
- Dr. Jayasree Patla  
Alexandria Healthcare  
6303 Little River Turnpike, Suite 160  
Alexandria, VA 22312  
(703) 658-2650

**OBJECTIONS TO INTERROGATORY NO. 10:**

Lilly objects to this Interrogatory to the extent it seeks information from third parties not in Lilly's possession. Otherwise, Lilly has no objection.

**INTERROGATORY NO. 11:**

Please list, by year, the total amount of payments, including but not limited to any compensation, gifts, payments, honoraria, or consulting fees, made to:

- Dr. Navera R. Ahmad  
Virginia Hospital Center  
1701 N. George Mason Drive  
Arlington, VA 22205  
(703) 525-3069
- Dr. Thonia Hafez Gab-Allah (retired)  
(571) 232-1309
- Dr. Jayasree Patla  
Alexandria Healthcare  
6303 Little River Turnpike, Suite 160  
Alexandria, VA 22312  
(703) 658-2650

**OBJECTIONS TO INTERROGATORY NO. 11:**

Lilly has no objection.

**INTERROGATORY NO. 12:**

Please list the title, date, duration, and location of any LILLY-sponsored education program that discussed CYMBALTA, attended by any of the following, divided by individual:

- Dr. Navera R. Ahmad  
Virginia Hospital Center  
1701 N. George Mason Drive  
Arlington, VA 22205  
(703) 525-3069
- Dr. Thonia Hafez Gab-Allah (retired)  
(571) 232-1309
- Dr. Jayasree Patla  
Alexandria Healthcare  
6303 Little River Turnpike, Suite 160  
Alexandria, VA 22312  
(703) 658-2650

**OBJECTIONS TO INTERROGATORY NO. 12:**

Lilly has no objection.

**INTERROGATORY NO. 13:**

Please explain, to the best of LILLY's knowledge, why adverse reactions sometimes occur upon the discontinuation of CYMBALTA treatment.

**OBJECTIONS TO INTERROGATORY NO. 13:**

Lilly objects to this Interrogatory to the extent it poses a complex medical question that does not lend itself to an answer in this format. Lilly will be responding by reference to documents, scientific articles, and prior testimony concerning this subject.

**INTERROGATORY NO. 14:**

Please explain LILLY's reason for changing the US LABEL concerning "Discontinuation of Treatment with Cymbalta" in 2008 from "the following symptoms occurred at a rate greater than or equal to 2%" to "the following symptoms occurred at a rate greater than or equal to 1%."

**OBJECTIONS TO INTERROGATORY NO. 14:**

Lilly has no objection.

**INTERROGATORY NO. 15:**

Please explain LILLY's reason for adding to the 2009 US CYMBALTA LABEL "or tapered" in the context of "Following abrupt ... discontinuation ..." in the section titled "Discontinuation of Treatment with Cymbalta."

**OBJECTIONS TO INTERROGATORY NO. 15:**

Lilly has no objection.

**INTERROGATORY NO. 16:**

Please explain LILLY's reason for changing the US CYMBALTA LABEL in 2012 from "the following symptoms occurred at a rate greater than or equal to 1%" to "at 1% or greater" in the section titled "Discontinuation of Treatment with Cymbalta."

**OBJECTIONS TO INTERROGATORY NO. 16:**

Lilly has no objection.

**INTERROGATORY NO. 17:**

Please explain the reason LILLY included in its labeling in European countries that adverse events seen on abrupt treatment discontinuation of CYMBALTA occurred in approximately 45% of patients treated with CYMBALTA, but did not disclose that information on the FDA-approved LABEL.

**OBJECTIONS TO INTERROGATORY NO. 17:**

Lilly objects to this Interrogatory to the extent that it is argumentative and mischaracterizes Lilly's actions or motives in the creation of its U.S. label for Cymbalta. Lilly will respond substantively to this Interrogatory as to the origin of the language in the European label ("SmPC").

**INTERROGATORY NO. 18:**

Provide the citation of every journal publication that LILLY sponsored, paid for, or was otherwise involved in creating, that relates to WITHDRAWAL associated with SSRIs or SNRIs, including but not limited to CYMBALTA, Prozac, Zoloft, Paxil, and Effexor.

**OBJECTIONS TO INTERROGATORY NO. 18:**

Lilly objects to this Interrogatory as overly broad and unduly burdensome as to time and scope and to the extent it is not limited to journal articles concerning Cymbalta. The Complaint does not allege that Plaintiff was treated with Prozac, Zoloft, Paxil, or Effexor, and as such, those medicines are irrelevant to this matter. Lilly also objects to this Interrogatory as Lilly-sponsored journal publications are available in the public domain, Lilly authors' involvement with those articles is reflected in a disclosure statement in each article, and Plaintiff can find the information it seeks through this Interrogatory through an online literature search. Lilly will not be compiling a list of journal articles for Plaintiff.

**INTERROGATORY NO. 19:**

Provide the citation of every journal publication that LILLY sponsored, paid for, or was otherwise involved in creating, that relates to CYMBALTA.

**OBJECTIONS TO INTERROGATORY NO. 19:**

Lilly objects to this Interrogatory as overly broad and unduly burdensome as to time and scope. Plaintiff already has the citations for the three principal articles reporting on Lilly-sponsored trials involving Cymbalta that address discontinuation-emergent adverse events, which are fully available in the public domain, Lilly authors' involvement with those articles is reflected in a disclosure statement in each article, and Plaintiff can find the information it seeks through this Interrogatory through an online literature search. Lilly will not be compiling a list of all journal articles relating to Cymbalta for Plaintiff.

**INTERROGATORY NO. 20:**

Provide the citation of every journal publication that LILLY sponsored, paid for, or was otherwise involved in creating, that relates to the down regulation of neurotransmitters and any SSRI or SNRI, including but not limited to CYMBALTA, Prozac, Zoloft, Paxil, and Effexor.

**OBJECTIONS TO INTERROGATORY NO. 20:**

See objections to Interrogatories Nos. 18 and 19. Lilly will not be compiling a list of journal articles for Plaintiff.

**INTERROGATORY NO. 21:**

List every placebo-controlled, active-controlled, and open-label clinical trial involving CYMBALTA, which contained a measurement designed to measure WITHDRAWAL, indicating for each trial: the date of the trial (started and completed); the location of the trial;

whether the trial was completed as part of an Investigational New Drug Application, and if so, its designation; whether the trial was published in a medical journal, and if so, the citation; and whether the results of the trial were shared with the FDA.

**OBJECTIONS TO INTERROGATORY NO. 21:**

Lilly objects to this Interrogatory as unduly burdensome as it assigns Lilly the burden of compiling and sorting voluminous amounts of clinical trial information. Plaintiff has access to Lilly's Investigational New Drug application and New Drug Application productions in the *Hexum/Herrera* actions, which include Cymbalta clinical trials, protocols, labeling, and regulatory correspondence located through a reasonably diligent search. Lilly will make a good faith effort to identify Cymbalta clinical trials relating to each New Drug Application and the corresponding Bates numbers in Lilly's existing voluminous production so Plaintiff can identify the specific information it seeks through this Interrogatory.

**INTERROGATORY NO. 22:**

Please state the amount of revenue, by year, that LILLY obtained from the sale of CYMBALTA within the United States between its approval in 2004 and the present.

**OBJECTIONS TO INTERROGATORY NO. 22:**

Lilly has no objection. Lilly will be responding to this Interrogatory by reference to publicly available information.

Respectfully Submitted,

Dated: February 23, 2015

By:                     /s/                      
Jeffrey T. Bozman (83679)  
Covington & Burling LLP  
One CityCenter  
850 Tenth Street, NW  
Washington, DC 20001  
Tel: (202) 662-5829  
Fax: (202) 778-5829  
*Counsel for Eli Lilly and Company*



**CERTIFICATE OF SERVICE**

I, Jeffrey T. Bozman, hereby certify that on the 23rd day of February, 2015, I have served Plaintiff's counsel in this action with a copy of Defendant's Objections to Plaintiff's First Set of Interrogatories by mailing a copy of the same by United States Mail, postage prepaid, and electronic mail to the following address:

Peter A. Miller  
**Miller Legal LLC**  
175 S. Pantops Drive, Third Floor  
Charlottesville, VA 2291  
Telephone (434) 529-6909  
Facsimile (888) 830-1488  
PMiller@MillerLegalLLC.com  
*Counsel for Janine Ali*

Dated: February 23, 2015

By:                     /s/                      
Jeffrey T. Bozman (83679)  
Covington & Burling LLP  
One CityCenter  
850 Tenth Street, NW  
Washington, DC 20001  
Tel: (202) 662-5829  
Fax: (202) 778-5829  
*Counsel for Eli Lilly and Company*

## Exhibit 3-C

**UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF VIRGINIA  
ALEXANDRIA DIVISION**

JANINE ALI

Plaintiff,

v.

ELI LILLY AND COMPANY, an Indiana  
corporation,

Defendant.

CASE NO.: 1:14-CV-01615

**DEFENDANT’S RESPONSE TO PLAINTIFF’S FIRST SET OF INTERROGATORIES**

Defendant Eli Lilly and Company (“Defendant” or “Lilly”) hereby submits its responses to Plaintiff’s First Set of Interrogatories, as follows:

**GENERAL STATEMENT**

The following responses are subject to Lilly’s Objections to Plaintiff’s First Set of Interrogatories served on February 23, 2015 pursuant to Federal Rule of Civil Procedure 33 and Local Civil Rule 26 and, for the sake of brevity, not repeated herein. Lilly has not fully completed its investigation of the facts relating to this case, its discovery, or its preparation for trial. Both discovery and independent investigation are ongoing. Therefore, all responses contained herein are based solely upon such information and documents as are both presently available and specifically known to Lilly. Lilly reserves the right to supplement these responses as discovery and this investigation proceed. Lilly’s responses are in accordance with the requirements of the Federal Rules of Civil Procedure, the Local Rules, and any applicable Court Orders.

## **RESPONSES TO INTERROGATORIES**

### **INTERROGATORY NO. 1:**

Please IDENTIFY all current and former employees or consultants who were involved in drafting, editing, creating, and submitting to the FDA, the sections of the US CYMBALTA LABEL titled “Discontinuation of Treatment with Cymbalta,” and/or “Dosage and Administration” or “Medication Administration” or “Information for Patients” (depending on year).

### **RESPONSE TO INTERROGATORY NO. 1:**

Subject to and without waiving its Objections to Plaintiff’s First Set of Interrogatories, Lilly responds that the key employees or consultants who played a significant role in or were responsible for the creation and updates of Cymbalta’s United States Physicians Package Insert (“U.S. label”) were Nayan Acharya, Mark Bangs, Bryan Boggs, Greg Brophy, Sharon Hoog, Anne Sakai-Robbins, Antonio Crucitti, Madeleine Wohlreich, and Matt Kuntz, Isabelle Murray.

### **INTERROGATORY NO. 2:**

Please IDENTIFY all LILLY current and former employees who worked on CYMBALTA in the following department/divisions/sections of LILLY:

- Global Scientific Communications and Information
- Regulatory Affairs
- The LILLY Answer Center
- US Brand Cymbalta Team
- Global Labeling Department
- Discovery and Early phase teams
- Global Medical Affairs
- Global Patient Safety
- Global/Product Development
- Neuroscience Strategy Group
- Any CYMBALTA-specific committee, team, or group

### **RESPONSE TO INTERROGATORY NO. 2:**

Lilly refers Plaintiff to its objections to this Interrogatory.

**INTERROGATORY NO. 3:**

For each category below, please IDENTIFY ten (10) current or former employees or consultants who are knowledgeable, at least in part, on the following topics. If an individual only has knowledge of a subpart of one of these topics, please explain:

- The marketing and advertising of CYMBALTA to MEDICAL PROFESSIONALS
- The marketing and advertising of CYMBALTA to consumers
- The drafting, editing, creating, and submitting to the FDA of the US CYMBALTA LABEL, with specific reference to the sections of the label titled “Discontinuation of Treatment with Cymbalta,” Dosage and Administration” or “Medication Administration” or “Information for Patients” (depending on year).
- The drafting, editing, creating, and submitting to the European Medicines Agency of the CYMBALTA LABEL, with specific reference to the sections of the label concerning WITHDRAWAL.
- CYMBALTA WITHDRAWAL
- Clinical trials related to CYMBALTA and WITHDRAWAL
- Domestic regulatory issues related to CYMBALTA
- Foreign regulatory issues related to CYMBALTA
- Educational programs for CYMBALTA
- Training of sales representatives relative to CYMBALTA

**RESPONSE TO INTERROGATORY NO. 3:**

Lilly refers Plaintiff to its objections to this Interrogatory.

**INTERROGATORY NO. 4:**

Please IDENTIFY all non-employee medical doctors retained, paid, or compensated in any way (directly or indirectly), by or on behalf of LILLY to present materials and information about CYMBALTA to other doctors, including but not limited to Key Opinion Leaders (KOLs), Thought Leaders and doctors on LILLY’s Speaker’s Bureau.

**RESPONSE TO INTERROGATORY NO. 4:**

Subject to and without waiving its Objections to Plaintiff’s First Set of Interrogatories, Lilly responds that information about non-employee doctors associated with Lilly in relation to

Cymbalta can be found in Faculty Reports, Contract Status Reports, and Activity Detail Reports within its existing production at CYM-02739356 - CYM-02777355.

**INTERROGATORY NO. 5:**

Please list, by year, the total amount of payments, including but not limited to any compensation, gifts, payments, honoraria, or consulting fees, made to those individuals identified in Interrogatory No. 4.

**RESPONSE TO INTERROGATORY NO. 5:**

Subject to and without waiving its Objections to Plaintiff's First Set of Interrogatories, Lilly refers Plaintiff to its response to Interrogatory No. 4

**INTERROGATORY NO. 6:**

Please IDENTIFY all third-party vendors used by LILLY to organize, create, and/or conduct for education programs wherein CYMBALTA was discussed.

**RESPONSE TO INTERROGATORY NO. 6:**

Subject to and without waiving its Objections to Plaintiff's First Set of Interrogatories, Lilly responds that Lilly-sponsored education programs are not branded with Cymbalta-specific content.

**INTERROGATORY NO. 7:**

Please IDENTIFY all third-parties that LILLY consulted with and/or hired to engage in direct-to-consumer advertising for CYMBALTA.

**RESPONSE TO INTERROGATORY NO. 7:**

Subject to and without waiving its Objections to Plaintiff's First Set of Interrogatories, Lilly responds that it used the advertising agency DraftFCB for direct-to-consumer advertising of Cymbalta from 2004 through 2013. Thereafter, the entity changed its name to FCB.

**INTERROGATORY NO. 8:**

Please IDENTIFY all third-parties that LILLY consulted with and/or hired to plan and/or publish medical journal articles related to CYMBALTA.

**RESPONSE TO INTERROGATORY NO. 8:**

Lilly refers Plaintiff to its objections to this Interrogatory.

**INTERROGATORY NO. 9:**

Please IDENTIFY all third-parties that LILLY consulted with and/or hired to engage in public relations related to CYMBALTA.

**RESPONSE TO INTERROGATORY NO. 9:**

Lilly refers Plaintiff to its objections to this Interrogatory.

**INTERROGATORY NO. 10:**

Please IDENTIFY all sales representatives employed by LILLY or by a third-party contracted by LILLY to provide information to MEDICAL PROFESSIONALS healthcare providers concerning CYMBALTA who visited the following:

- Dr. Navera R. Ahmad  
Virginia Hospital Center  
1701 N. George Mason Drive  
Arlington, VA 22205  
(703) 525-3069

- Dr. Thonia Hafez Gab-Allah (retired)  
(571) 232-1309
- Dr. Jayasree Patla  
Alexandria Healthcare  
6303 Little River Turnpike, Suite 160  
Alexandria, VA 22312  
(703) 658-2650

**RESPONSE TO INTERROGATORY NO. 10:**

Subject to and without waiving its Objections to Plaintiff's First Set of Interrogatories, Lilly responds that the following sales representatives visited Dr. Ahmad in relation to Cymbalta: Anneliesa Hundt and Cem Sakarya. The following sales representatives visited Dr. Patla in relation to Cymbalta: Jennifer Board, Courtney Cecere, and Laura Kurasiewicz. No Lilly-affiliated sales representatives visited Dr. Gab-Allah in relation to Cymbalta.

**INTERROGATORY NO. 11:**

Please list, by year, the total amount of payments, including but not limited to any compensation, gifts, payments, honoraria, or consulting fees, made to:

- Dr. Navera R. Ahmad  
Virginia Hospital Center  
1701 N. George Mason Drive  
Arlington, VA 22205  
(703) 525-3069
- Dr. Thonia Hafez Gab-Allah (retired)  
(571) 232-1309
- Dr. Jayasree Patla  
Alexandria Healthcare  
6303 Little River Turnpike, Suite 160  
Alexandria, VA 22312  
(703) 658-2650



**RESPONSE TO INTERROGATORY NO. 11:**

Lilly responds that no compensation has been paid by Lilly to Drs. Ahmad, Gab-Allah, or Patla.

**INTERROGATORY NO. 12:**

Please list the title, date, duration, and location of any LILLY-sponsored education program that discussed CYMBALTA, attended by any of the following, divided by individual:

- Dr. Navera R. Ahmad  
Virginia Hospital Center  
1701 N. George Mason Drive  
Arlington, VA 22205  
(703) 525-3069
- Dr. Thonia Hafez Gab-Allah (retired)  
(571) 232-1309
- Dr. Jayasree Patla  
Alexandria Healthcare  
6303 Little River Turnpike, Suite 160  
Alexandria, VA 22312  
(703) 658-2650

**RESPONSE TO INTERROGATORY NO. 12:**

Lilly responds that it has no record of attendance by Drs. Ahmad, Gab-Allah, or Patla at any Lilly-sponsored education program.

**INTERROGATORY NO. 13:**

Please explain, to the best of LILLY's knowledge, why adverse reactions sometimes occur upon the discontinuation of CYMBALTA treatment.

**RESPONSE TO INTERROGATORY NO. 13:**

Subject to and without waiving its Objections to Plaintiff's First Set of Interrogatories, Lilly responds that several biochemical mechanisms have been proposed to account for symptoms that can appear following discontinuation of antidepressant treatment. For discussion of some of these theories, Lilly refers Plaintiff to the expert report of Doug Jacobs served in the *Hexum/Herrera* actions at page 21; Lilly's Cymbalta medical information letters on discontinuation symptoms (*see, e.g.*, CYM-0172876 - CYM-01727884); and the following articles:

- Zajecka J, Tracy KA, and Mitchell S (1997), Discontinuation Symptoms After Treatment With Serotonin Reuptake Inhibitors: A Literature Review, *J. Clin. Psychiatry*, 58(7); 291-297.
- Blier P and Tremblay P (2006), Physiologic mechanisms underlying the antidepressant discontinuation syndrome, *J. Clin. Psychiatry*, 67(4): 8-13.
- Schatzberg AF, Blier P, Delgado PL, Fava M, Haddad PM and Shelton RC (2006), Antidepressant Discontinuation Syndrome: Consensus Panel Recommendations for Clinical Management and Additional Research, *J. Clin. Psychiatry*, 67(supp. 4):27-30.

**INTERROGATORY NO. 14:**

Please explain LILLY's reason for changing the US LABEL concerning "Discontinuation of Treatment with Cymbalta" in 2008 from "the following symptoms occurred at a rate greater than or equal to 2%" to "the following symptoms occurred at a rate greater than or equal to 1%."

**RESPONSE TO INTERROGATORY NO. 14:**

Lilly responds that in 2007 it changed the frequency cutoff in the U.S. label's section "Discontinuation of Treatment with Cymbalta" from 2% to 1% based on a review of its clinical trial database for all Cymbalta indications approved by FDA at the time. This review identified five additional discontinuation-emergent adverse events ("DEAEs") that would be reported using

a 1% frequency cutoff. Therefore the 1% cutoff was adopted in order to include those additional DEAEs in the label. In addition, a 1% cutoff was more consistent with the existing categories of adverse event reporting frequencies as set forth by the Council for International Organizations of Medical Sciences (“CIOMS”). *See* CYM-01111108 - CYM-01111178; CYM-01112815 - CYM-01112850; Deposition of Christine Phillips, July 18, 2014 at 207:14-209:24.

**INTERROGATORY NO. 15:**

Please explain LILLY’s reason for adding to the 2009 US CYMBALTA LABEL “or tapered” in the context of “Following abrupt ... discontinuation ...” in the section titled “Discontinuation of Treatment with Cymbalta.”

**RESPONSE TO INTERROGATORY NO. 15:**

Lilly responds that in 2007 it added “or tapered” to the U.S. label’s section “Discontinuation of Treatment with Cymbalta” based on a review of its clinical trial database of all Cymbalta indications approved by FDA at the time. Lilly felt that by this time, it had conducted an adequate number of studies measuring discontinuation-emergent adverse events in the context of tapered discontinuation (rather than only abrupt discontinuation) to warrant this addition to the label. *See* CYM-01113160 - CYM-01113267; Deposition of Christine Phillips, July 18, 2014 at 210:1-16.

**INTERROGATORY NO. 16:**

Please explain LILLY’s reason for changing the US CYMBALTA LABEL in 2012 from “the following symptoms occurred at a rate greater than or equal to 1%” to “at 1% or greater” in the section titled “Discontinuation of Treatment with Cymbalta.”

**RESPONSE TO INTERROGATORY NO. 16:**

Lilly responds that in 2010 it changed the phrase “at a rate greater than or equal to 1%” to “at 1% or greater” in the U.S. label’s section “Discontinuation of Treatment with Cymbalta” simply for grammatical reasons to shorten and improve clarity.

**INTERROGATORY NO. 17:**

Please explain the reason LILLY included in its labeling in European countries that adverse events seen on abrupt treatment discontinuation of CYMBALTA occurred in approximately 45% of patients treated with CYMBALTA, but did not disclose that information on the FDA-approved LABEL.

**RESPONSE TO INTERROGATORY NO. 17:**

Subject to and without waiving Lilly’s Objections to Plaintiff’s First Set of Interrogatories, Lilly responds that the European regulatory body required Lilly and all other manufacturers of antidepressants to update the respective Summary of Product Characteristics (“SPC”) for such medicines with “core SPC language” that was similar across all SSRIs and SNRIs. This class labeling language included a statement of the percentage of patients in clinical trials who had adverse events on discontinuation of Cymbalta and the percentage of patients taking placebo who experienced adverse events. *See* CYM-01865850 - CYM-01865854.

Although FDA had the exact same data as the European regulatory authorities, FDA did not make a parallel request or requirement for similar information in Cymbalta’s U.S. label. Instead, FDA required that all U.S. labels for SSRIs and SNRIs include a two-paragraph statement about discontinuation symptoms that had been reported during the marketing of

medicines in the class and instructions to taper patients off the medicine when stopping treatment.

**INTERROGATORY NO. 18:**

Provide the citation of every journal publication that LILLY sponsored, paid for, or was otherwise involved in creating, that relates to WITHDRAWAL associated with SSRIs or SNRIs, including but not limited to CYMBALTA, Prozac, Zoloft, Paxil, and Effexor.

**RESPONSE TO INTERROGATORY NO. 18:**

Lilly refers Plaintiff to its objections to this Interrogatory.

**INTERROGATORY NO. 19:**

Provide the citation of every journal publication that LILLY sponsored, paid for, or was otherwise involved in creating, that relates to CYMBALTA.

**RESPONSE TO INTERROGATORY NO. 19:**

Lilly refers Plaintiff to its objections to this Interrogatory.

**INTERROGATORY NO. 20:**

Provide the citation of every journal publication that LILLY sponsored, paid for, or was otherwise involved in creating, that relates to the down regulation of neurotransmitters and any SSRI or SNRI, including but not limited to CYMBALTA, Prozac, Zoloft, Paxil, and Effexor.

**RESPONSE TO INTERROGATORY NO. 20:**

Lilly refers Plaintiff to its objections to this Interrogatory and its objections to Interrogatories Nos. 18 and 19.

**INTERROGATORY NO. 21:**

List every placebo-controlled, active-controlled, and open-label clinical trial involving CYMBALTA, which contained a measurement designed to measure WITHDRAWAL, indicating for each trial: the date of the trial (started and completed); the location of the trial; whether the trial was completed as part of an Investigational New Drug Application, and if so, its designation; whether the trial was published in a medical journal, and if so, the citation; and whether the results of the trial were shared with the FDA.

**RESPONSE TO INTERROGATORY NO. 21:**

Subject to and without waiving its Objections to Plaintiff's First Set of Interrogatories, Lilly refers Plaintiff to Attachment A, which identifies the Bates numbers corresponding to Cymbalta clinical trials located through a reasonably diligent search of Lilly's existing production. They are organized generally according to the New Drug Application to which they relate and include, among others, clinical trials that measured discontinuation-emergent adverse events.

**INTERROGATORY NO. 22:**

Please state the amount of revenue, by year, that LILLY obtained from the sale of CYMBALTA within the United States between its approval in 2004 and the present.

**RESPONSE TO INTERROGATORY NO. 22:**

Lilly responds that its annual revenue from sales of Cymbalta in the United States is published in its annual financial reports, available at <https://investor.lilly.com/annuals.cfm>

Respectfully Submitted,

Dated: March 9, 2015

By: \_\_\_\_\_/s/  
Jeffrey T. Bozman (83679)  
Covington & Burling LLP  
One CityCenter  
850 Tenth Street, NW  
Washington, DC 20001  
Tel: (202) 662-5829  
Fax: (202) 778-5829  
*Counsel for Eli Lilly and Company*

VERIFICATION

Re: Ali v. Eli Lilly & Company

I, James Lootens , am Assistant Secretary of Eli Lilly and Company and am authorized to provide Verification of discovery responses. Some of the information and facts within the responses is not within my personal knowledge. Such information has been assembled by authorized employees and/or counsel of Lilly who have informed me that the information and facts are true and accurate. Therefore, I verify the foregoing Defendant's Responses to Plaintiff's First Set of Interrogatories as true and accurate.

I declare under penalty of perjury that the foregoing is true and accurate.

Executed on this 9 day of March, 2015.

  
James Lootens



UNITED STATES OF AMERICA

STATE OF INDIANA )

) SS

COUNTY OF MARION )

Before me, a Notary Public for Marion County, State of Indiana, personally appeared  
James Lockens and acknowledged the execution of the foregoing instrument  
this 9 day of March, 2015.

Heather Richards

NOTARY PUBLIC



Printed Name: Heather Richards

My Commission Expires: 4-29-16

Resident of: Johnson County

(SEAL)

**CERTIFICATE OF SERVICE**

I, Jeffrey T. Bozman, hereby certify that on the 9th day of March, 2015, I have served Plaintiff's counsel in this action with a copy of Defendant's Responses to Plaintiff's First Set of Interrogatories by mailing a copy of the same by United States Mail, postage prepaid, and electronic mail to the following address:

Peter A. Miller  
**Miller Legal LLC**  
175 S. Pantops Drive, Third Floor  
Charlottesville, VA 2291  
Telephone (434) 529-6909  
Facsimile (888) 830-1488  
PMiller@MillerLegalLLC.com  
*Counsel for Janine Ali*

Dated: March 9, 2015

By:                     /s/                      
Jeffrey T. Bozman (83679)  
Covington & Burling LLP  
One CityCenter  
850 Tenth Street, NW  
Washington, DC 20001  
Tel: (202) 662-5829  
Fax: (202) 778-5829  
*Counsel for Eli Lilly and Company*

## Exhibit 4-A

**UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF VIRGINIA  
ALEXANDRIA DIVISION**

GILDA HAGAN-BROWN

Plaintiff,

v.

ELI LILLY AND COMPANY, an Indiana  
corporation,

Defendant.

CASE NO.: 1:14-CV-01614-AJT-JFA

**PLAINTIFF'S FIRST SET OF REQUESTS FOR PRODUCTION OF DOCUMENTS**

**PROPOUNDING PARTY:** Plaintiff, Gilda Hagan-Brown

**RESPONDING PARTY:** Defendant Eli Lilly and Company

**SET NO.:** ONE

Plaintiff Gilda Hagan-Brown ("PLAINTIFF"), by and through her attorneys, and pursuant to Federal Rule of Civil Procedure 26 and 34, does hereby serve written requests upon Defendant Eli Lilly and Company ("Lilly") to produce for inspection and reproduction the following documents and things specified below at the offices of BAUM, HEDLUND, ARISTEI & GOLDMAN, P.C., 12100 Wilshire Boulevard, Suite 950, Los Angeles, CA 90025, in accordance with the following definitions and instructions and within thirty (30) days of service.

**DEFINITIONS**

The following definitions apply to each request below and are incorporated therein:

1. "ALL" means "any and all" and the word "any" means "any and all."
2. The term "CYMBALTA" means duloxetine hydrochloride, including any other name or trademark under which it is sold, domestically *or* abroad, marketed or produced,

including products sold, marketed, or produced by others if they do so with your permission, at your request, at your direction, with your acquiescence, and/or if you gain any benefit from their sales, marketing, or distribution.

3. The term “COMMUNICATION” means and refers to every method and manner of transmitting or receiving data, opinions, thoughts, inquiries, representations and other information, whether orally, in writing, electronically, or otherwise, between two or more persons or entities. Communications include drafts and other written information intended for communicating to another person, even if not ultimately transmitted to or received by another person.

4. The terms “CONCERNING,” “RELATING,” and/or “REGARDING” mean containing, alluding to, responding to, commenting upon, discussing, explaining, mentioning, analyzing, constituting, memorializing, comprising, repeating, incorporating, confirming, listing, evidencing, setting forth, summarizing, or characterizing, either directly or indirectly, in whole or in part.

5. The term “DEAE” means Discontinuation Emergent Adverse Event, and refers to any possible side effects or symptoms relating to discontinuing, withdrawing, or tapering from the use, consumption, or treatment with Cymbalta.

6. The term “WITHDRAWAL” includes discontinuation or tapering, as well as DEAEs, withdrawal symptoms, and any side effects of withdrawing, discontinuing, or tapering from CYMBALTA.

7. The term “DOCUMENT” shall have the broadest meaning possible under Rule 34 of the Federal Rules of Civil Procedure and includes all originals and drafts, in any and all languages, of any nature whatsoever, in your possession, custody or control, regardless of where

located, and include, but are not limited to, letters, correspondence, logs, drafts, contracts, prospective contracts, agreements, reports, records, studies, surveys, resolutions, tabulations, notes, summaries, memoranda, Electronically Stored Information (“ESI”), electronic mail (“email”), calendar or diary entries, handwritten notes, working papers, work sheets, spread sheets, diagrams, minutes of meetings, agendas, bulletins, periodicals, circulars, advertisements, notices, announcements, invoices, statements, checks (front and back), bank statements, ledgers, orders, vouchers, instructions, drawings, charts, graphs, manuals, brochures, pamphlets, schedules, telegrams, teletypes, photographs, audio tapes, voice-mail messages, videotapes, electronic recordings, facsimile transmissions, and information of whatever kind either stored on computers, including computer disks, hard drives and other media, or contained in any computer or information retrieval devices.

8. The terms “ELI LILLY,” “LILLY,” “YOU” or “YOUR” refer to Eli LILLY and Company, its respective officers, directors, employees, representatives, subsidiaries, and affiliates thereof, as well as all persons acting for, on behalf of, or in concert with Eli LILLY and Company’s behalf, including agents, attorneys, accountants, and investigators.

9. The term “FDA” means the United States Food & Drug Administration.

10. The term “INCLUDING” means “including, but not limited to.”

11. The term “LABEL” refers to the official prescribing information for the drug, including but not limited to the product insert and medication guides approved by the FDA or other foreign regulatory bodies.

12. The term “MEDICAL PROFESSIONAL” includes healthcare providers, prescribing doctors, non-prescribing doctors, physicians, pharmacists, nurses, and other individuals who provide healthcare services.

13. The term “PERAHIA ARTICLE” refers to David G. Perahia, *et al.*, *Symptoms Following Abrupt Discontinuation of Duloxetine Treatment in Patients with Major Depressive Disorder*, 89 J. Affective Disorders 207-12 (2005).

14. The term “SNRI” means serotonin norepinephrine reuptake inhibitor.

15. The term “SSRI” means selective serotonin reuptake inhibitor.

16. The use of the terms “or,” “and,” and “and/or” should be construed conjunctively and disjunctively for the broadest possible meaning.

17. The term “person” or “people” includes individuals, corporations, partnerships, associations, and other bodies and entities, as well as their representatives, agents, employees and attorneys.

18. The terms “research,” “study,” or “analysis,” when used as a noun mean and refer to any research, analysis, study, report, evaluation or assessment. The term research when used as a verb means to research, analyze, study, report, evaluate, or assess.

19. The term “use” means to “employ something for a purpose,” “to do something habitually,” “to consume something,” “to manipulate,” “to benefit from,” as well as to allow others to “use,” or acquiesce in others’ “use.”

20. The singular use of any term or phrase includes its plural, and the plural of any term or phrase includes its singular.

21. The use of any tense of any verb shall also include within its meaning all other tenses of that verb.

### **INSTRUCTIONS**

1. You must serve your responses and any objections within 30 days after being served the requests.

2. Each paragraph and subparagraph of each request should be construed independently, and not be referenced to any other paragraph or subparagraph of this request for purposes of limitation.

3. Pursuant to the Fed. R. Civ. P. 26(e), these requests are continuing in nature, so as to require a supplemental response to correct any incomplete or incorrect answer based on information you may become aware of between the time of your initial response and the time of trial.

4. In responding to these requests, you shall respond based on information in your possession, custody, or control, including (by way of illustration only and not limited to) information in the possession, custody, or control of your affiliates, subsidiaries, or subcontractors, your present or former attorneys, accountants, directors, officers, partners, employees, other representatives and agents, independent contractors over which or whom you have or have had control, and any other persons acting on your behalf.

5. Notwithstanding the assertion of any objection to production, any documents as to which an objection is raised that also contain non-objectionable matter that is relevant and material to a request herein must be produced, but that portion of the documents for which the objection is asserted may be redacted, provided that the material redacted is listed in the privilege log.

6. If you claim that the attorney-client privilege, or any other privilege, doctrine or reason for withholding a document is applicable, please set forth in writing and with your response to this Request: (1) the date of the document; (2) the type of document; (3) the subject matter of the document; (4) the name, employment and title of each person who prepared or received the document or any copy thereof; and (5) the basis for the claim of privilege or other



ground for withholding the document. If you claim only part of the document is privileged or otherwise need not be produced, please produce the remaining part of the document. In the case of attorney work-product privilege, you must also identify the litigation for which the work-product was prepared.

7. If any document to be produced has been lost, discarded, transferred to another person or entity, destroyed, or otherwise disposed of, please set forth in writing: (1) the date, name and subject matter of the document; (2) the name, employment and title of each person who prepared, received, reviewed, or had custody, possession, or control of the document; (3) all persons with knowledge of the contents or any portion of the contents of the document; (4) the previous location of the document; (5) the date of disposal or transfer of the document; (6) the reason for disposal or transfer of the document; and, if applicable, (7) the manner of disposal of the document; or, if applicable, (8) the names and addresses of the transferees of the document.

8. For the convenience of the Court and the parties, Plaintiffs request that each request be quoted in full immediately preceding the answer.

9. Whenever a reference to a business entity appears, the reference shall mean the business entity, its affiliated entities, partnerships, divisions, subdivisions, directors, officers, employees, agents, clients, or other representatives of affiliated third parties.

10. Unless specified by the request, there is no time limitation to any of these requests.

11. As provided by Federal Rule of Civil Procedure Rule 34(b)(2)(E)(iii), please produce all electronically stored information in their native electronic format with all metadata preserved in a \*.DAT file format. "Electronically stored information" includes the full scope of that term as contemplated by Federal Rule of Civil Procedure Rule 34, and refers to all computer

or electronically stored or generated data and information, and shall include all attachments to the enclosures with any requested item, to which they are attached or with which they are enclosed, and all drafts thereof. “Electronically stored information” includes, but is not limited to, all information stored in any format on any storage media, including for example, but not limited to: hard disks, floppy disks, optical disks, flash memory devices, and magnetic tape, whether fixed, portable, or removable. The format of “electronically stored information” includes, for example, but is not limited to: word processing documents, electronic spreadsheets, electronic presentation documents, email messages, image files, sound files, material or information stored in a database, or accessible from a database, of whatever description. “Electronically stored information” also includes all associated metadata that is routinely maintained or saved, which includes for example, but is not limited to document title or name, file name, date and time of creation, date and time of last edit, identity of author, identity of owner, identities of editors, identities of recipients, changes, history of changes, email header information, and email routing information.) Please produce all metadata in a \*.DAT file format. If a document contains a single redaction, please provide the appropriate metadata for the remainder of the document, notwithstanding the redactions and the information provided separately as part of a privilege log.

12. For the convenience of the parties and to reduce production costs, please produce all DOCUMENTS which exist only in hardcopy, i.e., cannot be produced in the electronic format discussed above, form in an electronic format such as a \*.PDF format or equivalent.

13. In response to each request, please specifically reference which Bates numbered pages are responsive to *that* request. Generalized reference to categories of documents is the equivalent of no response at all. If no DOCUMENTS are responsive, please indicate such. If

you are not responding to a request or any portion therein, please indicate such.

## **REQUESTS FOR PRODUCTION**

### **I. FDA DOCUMENTS**

#### **REQUEST FOR PRODUCTION NO. 1:**

Please produce the Electronic Common Technical Document (eCTD) or equivalent electronic submission for all CYMBALTA indications, whether that indication was approved or denied, including but not limited to: Major Depressive Disorder (MDD), Generalized Anxiety Disorder (GAD), Neuropathic Pain from Diabetes, Chronic Pain, Chronic Musculoskeletal Pain, Fibromyalgia, MDD Maintenance, GAD Maintenance, and Stress Urinary Incontinence (SUI).

#### **REQUEST FOR PRODUCTION NO. 2:**

Please produce the Summary Basis of Approval for CYMBALTA for the following indications: Major Depressive Disorder (MDD), Generalized Anxiety Disorder (GAD), Neuropathic Pain from Diabetes, Chronic Pain, Chronic Musculoskeletal Pain, Fibromyalgia, MDD Maintenance, and GAD Maintenance.

#### **REQUEST FOR PRODUCTION NO. 3:**

Please produce all Periodic Safety Updates regarding CYMBALTA for the following indications: Major Depressive Disorder (MDD), Generalized Anxiety Disorder (GAD), Neuropathic Pain from Diabetes, Chronic Pain, Chronic Musculoskeletal Pain, Fibromyalgia, MDD Maintenance, and GAD Maintenance.

#### **REQUEST FOR PRODUCTION NO. 4:**

Please produce all Annual Safety Updates regarding CYMBALTA for the following indications: Major Depressive Disorder (MDD), Generalized Anxiety Disorder (GAD), Neuropathic Pain from Diabetes, Chronic Pain, Chronic Musculoskeletal Pain, Fibromyalgia,

MDD Maintenance, and GAD Maintenance.

**REQUEST FOR PRODUCTION NO. 5:**

Please produce the electronic Investigational New Drug (“IND”) file for CYMBALTA.

**REQUEST FOR PRODUCTION NO. 6:**

Please produce all warning letters sent to YOU from the FDA regarding CYMBALTA.

**REQUEST FOR PRODUCTION NO. 7:**

Please produce YOUR responses to all warning letters sent to YOU from the FDA regarding CYMBALTA.

**REQUEST FOR PRODUCTION NO. 8:**

Please produce the transcript of any FDA Advisory Committee meetings regarding CYMBALTA for any indication.

**REQUEST FOR PRODUCTION NO. 9:**

Please produce any DOCUMENTS submitted to the FDA as part of any Advisory Committee meeting related to CYMBALTA.

**REQUEST FOR PRODUCTION NO. 10:**

Please produce any and all Form 483 and/or Warning Letters that YOU received from the FDA related to CYMBALTA.

**REQUEST FOR PRODUCTION NO. 11:**

Please produce YOUR responses to all Form 483 and/or Warning Letters that YOU received from the FDA related to CYMBALTA.

**REQUEST FOR PRODUCTION NO. 12:**

Please produce all DOCUMENTS reflecting any settlements, agreements, resolutions, fines, sanctions and/or additional regulatory actions that arose as a result of the Form 483 and/or

Warning Letters that YOU received from the FDA related to CYMBALTA.

**REQUEST FOR PRODUCTION NO. 13:**

Please produce all DOCUMENTS related to any COMMUNICATIONS with the FDA about CYMBALTA containing any of the following terms (or any derivative term): DEAE, withdrawal, discontinuation or discontinuing, dependence, habit-forming, addiction, quitting, tapering, brain zaps, electric shock, down regulation, half-life, missed dose, “greater than or equal to,” Perahia, Rosenbaum, or Schatzberg.

**REQUEST FOR PRODUCTION NO. 14:**

Please produce all DOCUMENTS related to any COMMUNICATIONS with the FDA about Prozac or fluoxetine containing any of the following terms (or any derivative term): DEAE, withdrawal, discontinuation or discontinuing, dependence, habit-forming, addiction, quitting, tapering, brain zaps, electric shock, down regulation, half-life, missed dose, “greater than or equal to,” Perahia, Rosenbaum, or Schatzberg.

**REQUEST FOR PRODUCTION NO. 15:**

Please produce all DOCUMENTS related to any COMMUNICATIONS with the FDA about Zyprexa or olanzapine containing any of the following terms (or any derivative term): DEAE, withdrawal, discontinuation or discontinuing, dependence, habit-forming, addiction, quitting, tapering, brain zaps, electric shock, down regulation, half-life, missed dose, “greater than or equal to,” Perahia, Rosenbaum, or Schatzberg.

**REQUEST FOR PRODUCTION NO. 16:**

Please produce all DOCUMENTS reflecting COMMUNICATIONS with the FDA about the section of the US LABEL titled “Discontinuation of Treatment with Cymbalta.”

**REQUEST FOR PRODUCTION NO. 17:**

Please produce all DOCUMENTS reflecting COMMUNICATIONS with the FDA about the sections of the US LABEL titled “Dosage and Administration” or “Medication Administration” or “Information for Patients” (depending on year).

**REQUEST FOR PRODUCTION NO. 18:**

Please produce all DOCUMENTS that reflect COMMUNICATIONS between LILLY and the FDA concerning LILLY’s Medical Information Letters, or similar letters, concerning the potential risk of withdrawal or discontinuation from CYMBALTA.

**REQUEST FOR PRODUCTION NO. 19:**

Please produce all COMMUNICATIONS between YOU and the FDA concerning the half-life of CYMBALTA.

**REQUEST FOR PRODUCTION NO. 20:**

Please produce all COMMUNICATIONS between YOU and the FDA concerning the enteric coating of CYMBALTA.

**REQUEST FOR PRODUCTION NO. 21:**

Please produce a copy of each FDA-approved version of the package insert for CYMBALTA used by LILLY since it began marketing CYMBALTA in the United States.

**REQUEST FOR PRODUCTION NO. 22:**

Please produce a copy of each version of the LABEL for CYMBALTA in each foreign country wherein CYMBALTA was approved for marketing in that country.

**REQUEST FOR PRODUCTION NO. 23:**

Please produce the electronic Adverse Event Reporting database for CYMBALTA.

## **II. INTERNAL COMMUNICATIONS ABOUT CYMBALTA**

### **REQUEST FOR PRODUCTION NO. 24:**

Please produce all DOCUMENTS reflecting LILLY's internal COMMUNICATIONS and/or deliberations concerning the section of the US CYMBALTA LABEL titled "Discontinuation of Treatment with Cymbalta," including not limited to all emails, memorandums, drafts, comments, edits, redlines, or discussions about those edits of those sections of the US CYMBALTA LABEL.

### **REQUEST FOR PRODUCTION NO. 25:**

Please produce all DOCUMENTS reflecting LILLY's internal COMMUNICATIONS and/or deliberations concerning the section of the US CYMBALTA LABEL titled "Dosage and Administration" or "Medication Administration" or "Information for Patients" (depending on year), including not limited to all emails, memorandums, drafts, comments, edits, redlines, or discussions about those edits of the that section of the US CYMBALTA LABEL.

### **REQUEST FOR PRODUCTION NO. 26:**

Please produce all DOCUMENTS reflecting LILLY's internal COMMUNICATIONS and/or deliberations concerning the following sentences in the US CYMBALTA LABEL as it was approved in 2004, including but not limited to all emails, memorandums, drafts, comments, edits, redlines, or discussions about those edits: "Duloxetine should be swallowed whole and should not be chewed or crushed, nor should the contents be sprinkled on food or mixed with liquids. All of these might affect the enteric coating."

### **REQUEST FOR PRODUCTION NO. 27:**

Please produce all DOCUMENTS that reflect LILLY's reason for changing the US LABEL concerning "Discontinuation of Treatment with Cymbalta" in 2008 from "the following

symptoms occurred at a rate greater than or equal to 2%” to “the following symptoms occurred at a rate greater than or equal to 1%.”

**REQUEST FOR PRODUCTION NO. 28:**

Please produce all DOCUMENTS that reflect LILLY’s reason for adding to the 2009 US CYMBALTA LABEL “or tapered” in the context of “Following abrupt ... discontinuation ...” in the section titled “Discontinuation of Treatment with Cymbalta.”

**REQUEST FOR PRODUCTION NO. 29:**

Please produce all DOCUMENTS that reflect LILLY’s reason for changing the US CYMBALTA LABEL in 2012 from “the following symptoms occurred at a rate greater than or equal to 1%” to “at 1% or greater” in the section titled “Discontinuation of Treatment with Cymbalta.”

**REQUEST FOR PRODUCTION NO. 30:**

Please produce all DOCUMENTS that reflect LILLY’s reason for creating CYMBALTA as capsules containing enteric-coated pellets of duloxetine hydrochloride.

**REQUEST FOR PRODUCTION NO. 31:**

Please produce all DOCUMENTS reflecting LILLY’s internal COMMUNICATIONS and/or deliberations concerning the design of CYMBALTA as enteric-coated pellets contained within a capsule.

**REQUEST FOR PRODUCTION NO. 32:**

Please produce all DOCUMENTS reflecting LILLY’s internal COMMUNICATIONS and/or deliberations concerning the development of a dosage of CYMBALTA below 20mg.

**REQUEST FOR PRODUCTION NO. 33:**

Please produce all DOCUMENTS reflecting LILLY’s internal COMMUNICATIONS



and/or deliberations concerning the development of CYMBALTA as a scored tablet.

**REQUEST FOR PRODUCTION NO. 34:**

Please produce all memoranda, presentations, and/or reports, whether prepared internally or provided to LILLY by a third-party, that discuss, in any way, CYMBALTA and WITHDRAWAL.

**REQUEST FOR PRODUCTION NO. 35:**

Please produce all electronic mail ("email") for the individuals identified in Interrogatory Nos. 1 & 3, whether internal or external and whether on LILLY's current computer operating system, on individual employees' laptop computers, or archive systems, which contain at least one of the following terms:

**Cy!, dulo!, Aricclaim, Xeristar, Yentreve, Duzela, Dulane, Cymgen, Prozac, Fluox!, Paxil, Parox!, Zoloft, Sertra!, Celexa, Citalop!, Lexapro, Escitalop!, Effexor, venlafa!, Pristiq, desvenlafax!, milnacipr!, levomilnacipr!, SSRI!, SNRI!, or anti!,**

*and* at least one of the following terms:

**DEAE!, discon!, withd!, taper!, cold w/1turkey, addict!, habit!, paresth!, zap!, electric w/4 shock, dizz!, Rosenbaum, Schatzberg, Glenmullen, half-life, "missed dose," downregu!, "greater than or equal to," Perahia, enteric, pellets, "delayed release."**

**REQUEST FOR PRODUCTION NO. 36:**

Please produce all DOCUMENTS that reflect LILLY's internal COMMUNICATIONS and/or deliberations concerning any and all letters used by LILLY to respond to inquiries regarding CYMBALTA and DEAEs, discontinuation, withdrawal, dependence, or addiction.

**REQUEST FOR PRODUCTION NO. 37:**

Please produce all DOCUMENTS that reflect LILLY's internal COMMUNICATIONS

and/or deliberations concerning any of LILLY's Medical Information Letters, or similar letters, concerning the potential risk of withdrawal or discontinuation from CYMBALTA.

**REQUEST FOR PRODUCTION NO. 38:**

Please produce all minutes of meetings of any LILLY committee, working group, department, board, etc. where CYMBALTA and WITHDRAWAL were discussed.

**REQUEST FOR PRODUCTION NO. 39:**

Please produce all DOCUMENTS that reflect LILLY's internal COMMUNICATIONS and/or deliberations concerning why the rate of WITHDRAWAL reflected in the PERAHIA article was not included in the US LABEL.

**REQUEST FOR PRODUCTION NO. 40:**

Please produce all DOCUMENTS that reflect LILLY's internal COMMUNICATIONS and/or deliberations concerning why the rate of WITHDRAWAL reflected in the PERAHIA article was included in the European LABEL.

**REQUEST FOR PRODUCTION NO. 41:**

Please produce all DOCUMENTS that reflect LILLY's internal COMMUNICATIONS concerning discontinuation or withdrawal symptoms upon discontinuation of Effexor, including but not limited to any discussion concerning the language contained in the US Effexor LABEL concerning WITHDRAWAL.

**III. COMMUNICATIONS WITH MEDICAL PROFESSIONALS**

**REQUEST FOR PRODUCTION NO. 42:**

Please produce any "Dear Healthcare Professional" or similar letters to doctors, pharmacies or other groups, organizations about CYMBALTA.

**REQUEST FOR PRODUCTION NO. 43:**

Please produce all DOCUMENTS that contain a record or description of COMMUNICATIONS to LILLY from MEDICAL PROFESSIONALS or the public, including but not limited to call logs, inquiring about CYMBALTA that mention DEAEs, withdrawal, discontinuation or discontinuing, dependence, habit-forming, addiction, quitting, tapering, brain zaps, electric shock, down regulation, half-life (or any related or derivative terms).

**REQUEST FOR PRODUCTION NO. 44:**

Please produce any and all letters used by LILLY to respond to inquiries regarding CYMBALTA and DEAEs, discontinuation, withdrawal, dependence, or addiction.

**REQUEST FOR PRODUCTION NO. 45:**

Please produce a copy of each and every version of LILLY's "Medical Information Letter" or similar letters to doctors, pharmacies or other groups, organizations or entities discussing the potential risk of withdrawal or discontinuation from CYMBALTA.

**REQUEST FOR PRODUCTION NO. 46:**

Please produce all DOCUMENTS that identify MEDICAL PROFESSIONALS to whom LILLY sent a Medical Information Letter concerning the potential risk of withdrawal or discontinuation from CYMBALTA (e.g., an Excel spreadsheet or Access spreadsheet).

**REQUEST FOR PRODUCTION NO. 47:**

Please produce any and all DOCUMENTS that reflect each inquiry from a MEDICAL PROFESSIONAL concerning Cymbalta and withdrawal or discontinuation, including but not limited to written letters, telephone calls, online requests, sales representative relay.

**IV. MEDICAL LITERATURE AND CONTINUING MEDICAL EDUCATION**

**REQUEST FOR PRODUCTION NO. 48:**

Please produce all publication plans for CYMBALTA, whether prepared internally or by a third-party.

**REQUEST FOR PRODUCTION NO. 49:**

Please produce all DOCUMENTS reflecting LILLY's involvement in the drafting, editing, and publication the PERAHIA ARTICLE, including but not limited to all email communications, article drafts, and publication plans relating to the PERAHIA ARTICLE.

**REQUEST FOR PRODUCTION NO. 50:**

Please produce the study protocol and final study reports for each of the CYMBALTA trials discussed in the PERAHIA ARTICLE.

**REQUEST FOR PRODUCTION NO. 51:**

Please produce the raw data, including but not limited to the case report forms for each of the CYMBALTA trials discussed in the PERAHIA ARTICLE.

**REQUEST FOR PRODUCTION NO. 52:**

Please produce all DOCUMENTS reflecting the amount of compensation given to the authors of the PERAHIA ARTICLE, including but not limited to non-listed authors in the final publication.

**REQUEST FOR PRODUCTION NO. 53:**

Please produce a copy of the articles identified in Interrogatories Nos. 18 &19.

**REQUEST FOR PRODUCTION NO. 54:**

Please produce all DOCUMENTS reflecting LILLY's involvement in the drafting, editing, and publication of those articles identified in Interrogatories Nos. 18 &19.

**REQUEST FOR PRODUCTION NO. 55:**

Please produce all DOCUMENTS reflecting the amount of compensation given to the authors of those articles identified in Interrogatories Nos. 18 &19, including but not limited to compensation associated with the article's publication. In lieu of producing these documents, Plaintiff would accept an Excel chart listing each author and the total amount of compensation received by that author by LILLY, by year.

**REQUEST FOR PRODUCTION NO. 56:**

Please produce all DOCUMENTS reflecting any communications between LILLY and the authors of the articles identified in Interrogatories Nos. 18 &19 concerning discontinuation or withdrawal symptoms upon discontinuation of any SSRI or SNRI, including but not limited to CYMBALTA, Effexor, Prozac, Paxil and Zoloft.

**REQUEST FOR PRODUCTION NO. 57:**

Please produce all DOCUMENTS reflecting any COMMUNICATIONS between LILLY and Mario Fava concerning discontinuation or withdrawal symptoms upon discontinuation of any SSRI or SNRI, including but not limited to CYMBALTA, Effexor, Prozac, Paxil and Zoloft.

**REQUEST FOR PRODUCTION NO. 58:**

Please produce all DOCUMENTS reflecting any COMMUNICATIONS between LILLY and Jerrold Rosenbaum concerning discontinuation or withdrawal symptoms upon discontinuation of any SSRI or SNRI, including but not limited to CYMBALTA, Effexor, Prozac, Paxil and Zoloft.

**REQUEST FOR PRODUCTION NO. 59:**

Please produce all DOCUMENTS reflecting any COMMUNICATIONS between LILLY and Peter Haddad concerning discontinuation or withdrawal symptoms upon discontinuation of

any SSRI or SNRI, including but not limited to CYMBALTA, Effexor, Prozac, Paxil and Zoloft.

**REQUEST FOR PRODUCTION NO. 60:**

Please produce all DOCUMENTS reflecting any communications between LILLY and Alan Schatzberg concerning discontinuation or withdrawal symptoms upon discontinuation of any SSRI or SNRI, including but not limited to CYMBALTA, Effexor, Prozac, Paxil and Zoloft.

**REQUEST FOR PRODUCTION NO. 61:**

Please produce all CYMBALTA clinical trials wherein DEAEs or withdrawal symptoms were measured, noted, calculated, or where data concerning DEAEs or withdrawal was obtained, regardless of whether measuring DEAEs or withdrawal symptoms was part of the trial's original protocol. Please note this request is not limited in time (i.e., pre-approval or post-approval), geography (i.e., location of the study or clinical trial), type (i.e., placebo-controlled, active-controlled, or open), authorship (i.e., LILLY-sponsored or conducted by a third-party), or whether the trial was FDA-sanctioned. This request seeks all DEAE or withdrawal clinical data within LILLY's possession.

**REQUEST FOR PRODUCTION NO. 62:**

Please produce any presentations, PowerPoint presentations, memoranda, product brochures / marketing materials, and/or audio/video recordings, used by LILLY with regard to CYMBALTA that mention the potential risk of withdrawal or discontinuation from CYMBALTA.

**REQUEST FOR PRODUCTION NO. 63:**

Please produce all Continuing Medical Education ("CME") presentations or programs, including those DOCUMENTS given to attendees of CMEs, sponsored or created by YOU that mention DEAEs, withdrawal, discontinuation, dependence or addiction, whether related to

CYMBALTA or not, including but not limited to presentations that reference Prozac / fluoxetine and/or Effexor / venlafaxine.

**REQUEST FOR PRODUCTION NO. 64:**

Please produce DOCUMENTS which list, in whatever interval those lists were compiled, key opinion leaders / thought leaders related to CYMBALTA.

**REQUEST FOR PRODUCTION NO. 65:**

Please produce all DOCUMENTS reflecting any agreement with a key opinion leader / thought leader related to CYMBALTA.

**REQUEST FOR PRODUCTION NO. 66:**

Please produce all DOCUMENTS reflecting any compensation given to a key opinion leader / thought leader related to CYMBALTA.

**V. SALES AND MARKETING**

**REQUEST FOR PRODUCTION NO. 67:**

Please produce all television commercials for CYMBALTA.

**REQUEST FOR PRODUCTION NO. 68:**

Please produce all radio commercials for CYMBALTA.

**REQUEST FOR PRODUCTION NO. 69:**

Please produce all advertisements in magazines for CYMBALTA.

**REQUEST FOR PRODUCTION NO. 70:**

Please produce all advertisements on the internet for CYMBALTA.

**REQUEST FOR PRODUCTION NO. 71:**

Please produce all press releases ever issued by LILLY with regard to CYMBALTA.

**REQUEST FOR PRODUCTION NO. 72:**

Please produce all COMMUNICATIONS with WebMD regarding CYMBALTA.

**REQUEST FOR PRODUCTION NO. 73:**

Please produce every marketing plan, including all drafts, for CYMBALTA, regardless of whether that plan was prepared internally or by a third-party.

**REQUEST FOR PRODUCTION NO. 74:**

Please produce any report or DOCUMENT reflecting the effectiveness of LILLY's marketing campaigns for CYMBALTA.

**REQUEST FOR PRODUCTION NO. 75:**

Please produce every business plan, including all drafts, for CYMBALTA, regardless of whether that plan was prepared internally or by a third-party.

**REQUEST FOR PRODUCTION NO. 76:**

Please produce every launch plan, including all drafts, for CYMBALTA, regardless of whether that plan was prepared internally or by a third-party.

**REQUEST FOR PRODUCTION NO. 77:**

Please produce all COMMUNICATIONS between LILLY and any third-party marketing company or consultant concerning CYMBALTA's direct-to-consumer marketing that discusses, in any way, WITHDRAWAL.

**REQUEST FOR PRODUCTION NO. 78:**

Please produce all COMMUNICATIONS between LILLY and any third-party marketing company or consultant concerning CYMBALTA's direct-to-consumer marketing that discusses, in any way, once-a-day versus twice-a-day dosing.



**REQUEST FOR PRODUCTION NO. 79:**

Please produce all DOCUMENTS reflecting any contract or agreement between LILLY and a third-party company or consultant related to CYMBALTA's direct-to-consumer marketing.

**REQUEST FOR PRODUCTION NO. 80:**

Please produce all market surveys and focus group results / summaries for CYMBALTA.

**REQUEST FOR PRODUCTION NO. 81:**

Please produce all versions of materials and DOCUMENTS, including but not limited to videos or audio recordings, used to train LILLY pharmaceutical representatives about CYMBALTA.

**REQUEST FOR PRODUCTION NO. 82:**

Please produce DOCUMENTS reflecting LILLY's policies and practices regarding communicating with a MEDICAL PROFESSIONAL by a LILLY pharmaceutical representative.

**REQUEST FOR PRODUCTION NO. 83:**

Please produce exemplars of samples of CYMBALTA that were left with MEDICAL PROFESSIONALS by LILLY pharmaceutical representatives.

**REQUEST FOR PRODUCTION NO. 84:**

Please produce all marketing or promotional materials used with MEDICAL PROFESSIONALS by LILLY pharmaceutical representatives, regardless of whether that material was left with the MEDICAL PROFESSIONAL or not.

**REQUEST FOR PRODUCTION NO. 85:**

Please produce DOCUMENTS reflecting LILLY's policies and practices regarding the showing of medical journal articles to MEDICAL PROFESSIONALS by a LILLY

pharmaceutical representative.

**REQUEST FOR PRODUCTION NO. 86:**

Please produce all medical journal articles used by LILLY pharmaceutical representatives to promote CYMBALTA.

**REQUEST FOR PRODUCTION NO. 87:**

Please produce all DOCUMENTS that reflect COMMUNICATIONS between LILLY and the media about CYMBALTA and WITHDRAWAL.

**VI. CLIENT-SPECIFIC REQUESTS**

**REQUEST FOR PRODUCTION NO. 88:**

Please produce all DOCUMENTS reflecting any COMMUNICATION between LILLY and the following:

- Dr. Mohammed Bahadori (prescriber)  
Arthritis Care Center, P.C.  
14904 Jefferson Davis Hwy, Suite 203  
Woodbridge, VA 22192  
(703) 492-6660

**REQUEST FOR PRODUCTION NO. 89:**

Please produce the custodial file, including but not limited to employment agreements, termination agreements, performance reviews, self-reviews, W-2s, and bonus amounts, for each pharmaceutical representative who called upon the following:

- Dr. Mohammed Bahadori (prescriber)  
Arthritis Care Center, P.C.  
14904 Jefferson Davis Hwy, Suite 203  
Woodbridge, VA 22192  
(703) 492-6660

**REQUEST FOR PRODUCTION NO. 90:**

Please produce all records, entries, or other data from YOUR pharmaceutical

representative database, or any other electronic database used to track sales calls to physicians, regarding each and every sales call made to following:

- Dr. Mohammed Bahadori (prescriber)  
Arthritis Care Center, P.C.  
14904 Jefferson Davis Hwy, Suite 203  
Woodbridge, VA 22192  
(703) 492-6660

**REQUEST FOR PRODUCTION NO. 91:**

Please produce all DOCUMENTS reflecting any compensation, gifts, payments, honoraria, or consulting fees given by LILLY to the following:

- Dr. Mohammed Bahadori (prescriber)  
Arthritis Care Center, P.C.  
14904 Jefferson Davis Hwy, Suite 203  
Woodbridge, VA 22192  
(703) 492-6660

**REQUEST FOR PRODUCTION NO. 92:**

Please produce any written agreements, contracts, liability releases, or other legal documents that have been drafted and/or executed between LILLY or any third-party representing LILLY and the following:

- Dr. Mohammed Bahadori (prescriber)  
Arthritis Care Center, P.C.  
14904 Jefferson Davis Hwy, Suite 203  
Woodbridge, VA 22192  
(703) 492-6660

**REQUEST FOR PRODUCTION NO. 93:**

Please produce all DOCUMENTS, including but not limited to marketing materials, brochures, sales aids, “slim jims,” “skiffs,” clinical trials / medical journal articles, PowerPoint presentations, etc., that were given or shown by LILLY pharmaceutical representatives to the following:

- Dr. Mohammed Bahadori (prescriber)  
Arthritis Care Center, P.C.  
14904 Jefferson Davis Hwy, Suite 203  
Woodbridge, VA 22192  
(703) 492-6660

**REQUEST FOR PRODUCTION NO. 94:**

Please produce all DOCUMENTS reflecting participation in any LILLY-sponsored educational or sales program involving CYMBALTA by the following:

- Dr. Mohammed Bahadori (prescriber)  
Arthritis Care Center, P.C.  
14904 Jefferson Davis Hwy, Suite 203  
Woodbridge, VA 22192  
(703) 492-6660

**REQUEST FOR PRODUCTION NO. 95:**

Please produce, for the request above, all materials, including but not limited to PowerPoint presentations, syllabus, medical journal articles, summaries, agendas, etc., provided to or shown as part of the LILLY-sponsored program.

**REQUEST FOR PRODUCTION NO. 96:**

Please produce all records in YOUR possession related to Plaintiff. Please note that this request is in no way limited to medical or psychiatric records, but includes any DOCUMENTS obtained from a third-party by LILLY about the Plaintiff.

**REQUEST FOR PRODUCTION NO. 97:**

Please produce all DOCUMENTS reflecting any correspondence created in collecting the records described in the above request.

**VII. OTHER REQUESTS**

**REQUEST FOR PRODUCTION NO. 98:**

Please produce all DOCUMENTS identified in YOUR answers to all of Plaintiff's

Interrogatories.

**REQUEST FOR PRODUCTION NO. 99:**

Please produce all DOCUMENTS from which YOU obtained answers in responding to all of Plaintiff's Interrogatories.

**REQUEST FOR PRODUCTION NO. 100:**

Please produce the custodial file, including but not limited to employment agreements, termination agreements, performance reviews, self-reviews, W-2s, and bonus amounts, for each individual presented by LILLY as a person most knowledgeable under Federal Rule of Civil Procedure 30(b)(6).

**REQUEST FOR PRODUCTION NO. 101:**

Please produce all electronic mail ("email") for the individuals presented by LILLY as a person most knowledgeable under Federal Rule of Civil Procedure 30(b)(6), whether internal or external and whether on LILLY's current computer operating system, on individual employees' laptop computers, or archive systems, which contain at least one of the following terms:

**Cy!, dulo!, Aricclaim, Xeristar, Yentreve, Duzela, Dulane, Cymgen, Prozac, Fluox!, Paxil, Parox!, Zolof, Sertra!, Celexa, Citalop!, Lexapro, Escitalop!, Effexor, venlafa!, Pristiq, desvenlafax!, milnacipr!, levomilnacipr!, SSRI!, SNRI!, or anti!,**

*and* at least one of the following terms:

**DEAE!, discon!, withd!, taper!, cold w/1turkey, addict!, habit!, paresth!, zap!, electric w/4 shock, dizz!, Rosenbaum, Schatzberg, Glenmullen, half-life, "missed dose," downregu!, "greater than or equal to," Perahia, enteric, or time-release.**

**REQUEST FOR PRODUCTION NO. 102:**

Please produce all DOCUMENTS in LILLY's possession, custody or control concerning

any governmental investigations of LILLY in relation to CYMBALTA and, in any way, with  
WITHDRAWAL.

**REQUEST FOR PRODUCTION NO. 103:**

With respect to Lilly's Patient Assistance and/or Lilly Cares Program for CYMBALTA, please produce all documents regarding Lilly's decision to establish the program; its structure and budget; its criteria for deciding which patients qualify for the program; and any complaints, questions, or comments received from participants, physicians, or pharmacies.

**REQUEST FOR PRODUCTION NO. 104:**

Please produce all DOCUMENTS pertaining to Lilly's provision of CYMBALTA to Plaintiff, if applicable, as part of Lilly's Patient Assistance and/or Lilly Cares program.

**REQUEST FOR PRODUCTION NO. 105:**

Please produce all Corporate Integrity Agreements LILLY has entered into with any government for any reason.

Dated: February 4, 2015

Respectfully submitted,  
**MILLER LEGAL, LLC**

/s/ Brielle M. Hunt  
Brielle M. Hunt  
Miller Legal, LLC  
175 South Pantops Drive, Ste. 301  
Charlottesville, Virginia 22911  
Tel: (434) 529-6909  
Fax: (800) 768-9542  
Email: [bhunt@millerlegalllc.com](mailto:bhunt@millerlegalllc.com)

-and-

**BAUM HEDLUND ARISTEI & GOLDMAN,  
P.C.**

/s/ R. Brent Wisner  
Brent Wisner, Esq. (*pro hac vice*)  
12100 Wilshire Blvd., Suite 950

Los Angeles, CA 90025

(310) 207-3233

(310) 207-4204 (fax)

Email: [rbwisner@baumgedlundlaw.com](mailto:rbwisner@baumgedlundlaw.com)

**CERTIFICATE OF SERVICE**

I hereby certify that on this 4<sup>th</sup> day of February, 2015, a true and correct copy of the foregoing **PLAINTIFF'S FIRST SET OF REQUESTS FOR PRODUCTION OF DOCUMENTS** was served via Electronic Mail, upon the following:

Jeffrey Todd Bozman  
Brett C. Reynolds (pro hac vice)  
Michael X. Imbroscio (pro hac vice)  
Phyllis A. Jones (pro hac vice)  
**COVINGTON & BURLING LLP**  
One City Center  
850 Tenth Street, NW  
Washington, DC 20001  
Email: [jbozman@cov.com](mailto:jbozman@cov.com)  
Email: [breynolds@cov.com](mailto:breynolds@cov.com)  
Email: [mimbrosio@cov.com](mailto:mimbrosio@cov.com)  
Email: [pajones@cov.com](mailto:pajones@cov.com)

*Attorneys for Eli Lilly and Company*

/s/

\_\_\_\_\_  
Samantha Jison



## Exhibit 4-B

**UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF VIRGINIA  
ALEXANDRIA DIVISION**

GILDA HAGAN-BROWN

Plaintiff,

v.

ELI LILLY AND COMPANY, an Indiana  
corporation,

Defendant.

CASE NO.: 1:14-CV-01614-AJT-JFA

**DEFENDANT’S OBJECTIONS TO PLAINTIFF’S FIRST SET OF REQUESTS FOR  
PRODUCTION OF DOCUMENTS**

Defendant Eli Lilly and Company (“Defendant” or “Lilly”) hereby submits its objections to Plaintiff’s First Set of Requests for Production, as follows:

**GENERAL STATEMENTS AND OBJECTIONS**

Lilly objects to these Requests as overly broad, unduly burdensome, and not in proportion to the needs of the case, particularly to the extent they seek documents or information that are already in Plaintiff’s possession, custody, or control. Lilly has produced more than 2.5 million documents in *Hexum v. Eli Lilly & Co.*, Case No. 2:12-cv-2701-SVW (MAN) (C.D. Cal) and *Herrera v. Eli Lilly & Co.*, Case No. 2:12-cv-2702-SVW (MAN) (C.D. Cal.) (the “*Hexum/Herrera* actions”), pending actions concerning discontinuation-emergent adverse events allegedly arising from treatment with Cymbalta, the same subject matter as the allegations in this litigation. Plaintiff has access to those productions, yet Plaintiff has propounded these 105 Requests, broadly seeking documents that are contained in Lilly’s productions, are available in the public domain, or are of marginal relevance in this action. The purpose of the parties’

agreement to grant Plaintiff access to Lilly's productions in the *Hexum/Herrera* actions was to obviate the need for such extensive, burdensome discovery in this matter.

### **OBJECTIONS TO DEFINITIONS AND INSTRUCTIONS**

1. Lilly objects to the definitions of the terms "ELI LILLY", "LILLY", "YOU", and "YOUR" to the extent that they seek to extend these definitions to persons or entities other than the named Defendant in this litigation, Eli Lilly and Company, and purport to call for information or documents that are not in the possession, custody, or control of Eli Lilly and Company. For purposes of its objections and responses, Lilly will define "ELI LILLY", "LILLY", "YOU", and "YOUR" to mean Eli Lilly and Company. Lilly will limit its responses to information and documents that are in the possession, custody, or control of Eli Lilly and Company.

2. Lilly objects to the definition of "DOCUMENT" to the extent that it imposes obligations on Lilly beyond those in the Federal Rules of Civil Procedure.

3. Lilly objects to Instruction Number 1 to the extent that it does not comport with the Federal Rules of Civil Procedure and the Local Civil Rules of the Eastern District of Virginia.

4. Lilly objects to Instruction Number 7 to the extent that it imposes burdens on Lilly beyond its obligations under the Federal Rules of Civil Procedure.

5. Lilly objects to Instruction Number 11 to the extent that its use of the term "Electronically stored information" imposes burdens on Lilly beyond its obligations under the Federal Rules of Civil Procedure. Lilly also objects to the extent that this Instruction calls for the search and production of information from, including but not limited to, "hard disks, floppy disks, optical disks, flash memory devices, and magnetic tape, whether fixed, portable, or

removable.” A search of such sources and production of such data is overly broad, unduly burdensome, and not calculated to lead to the discovery of admissible evidence.

6. Lilly objects to Instruction Number 13 to the extent that it imposes burdens on Lilly beyond its obligations under the Federal Rules of Civil Procedure.

## **SPECIFIC OBJECTIONS TO REQUESTS FOR PRODUCTION**

### **I. FDA DOCUMENTS**

#### **REQUEST FOR PRODUCTION NO. 1:**

Please produce the Electronic Common Technical Document (eCTD) or equivalent electronic submission for all CYMBALTA indications, whether that indication was approved or denied, including but not limited to: Major Depressive Disorder (MDD), Generalized Anxiety Disorder (GAD), Neuropathic Pain from Diabetes, Chronic Pain, Chronic Musculoskeletal Pain, Fibromyalgia, MDD Maintenance, GAD Maintenance, and Stress Urinary Incontinence (SUI).

#### **OBJECTIONS TO REQUEST FOR PRODUCTION NO. 1:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request and its use of “Electronic Common Technical Document (eCTD)” as vague and ambiguous. Lilly construes “Electronic Common Technical Document (eCTD)” to mean Lilly’s Investigational New Drug (“IND”) submission and New Drug Application (“NDA”) submissions to FDA for Cymbalta indications. Subject to the foregoing objections, Lilly will direct Plaintiff within its prior productions to documents from its IND/NDA submissions to FDA for Cymbalta.

**REQUEST FOR PRODUCTION NO. 2:**

Please produce the Summary Basis of Approval for CYMBALTA for the following indications: Major Depressive Disorder (MDD), Generalized Anxiety Disorder (GAD), Neuropathic Pain from Diabetes, Chronic Pain, Chronic Musculoskeletal Pain, Fibromyalgia, MDD Maintenance, and GAD Maintenance.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 2:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request to the extent it seeks publicly available information given that the Summary Basis of Approval is an FDA created document available on FDA's website.

**REQUEST FOR PRODUCTION NO. 3:**

Please produce all Periodic Safety Updates regarding CYMBALTA for the following indications: Major Depressive Disorder (MDD), Generalized Anxiety Disorder (GAD), Neuropathic Pain from Diabetes, Chronic Pain, Chronic Musculoskeletal Pain, Fibromyalgia, MDD Maintenance, and GAD Maintenance.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 3:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Subject to the foregoing objections, Lilly will direct Plaintiff within its prior production to its Periodic Safety Update Reports.

**REQUEST FOR PRODUCTION NO. 4:**

Please produce all Annual Safety Updates regarding CYMBALTA for the following indications: Major Depressive Disorder (MDD), Generalized Anxiety Disorder (GAD), Neuropathic Pain from Diabetes, Chronic Pain, Chronic Musculoskeletal Pain, Fibromyalgia, MDD Maintenance, and GAD Maintenance.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 4:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request and its use of “Annual Safety Updates” as vague and ambiguous. Lilly construes “Annual Safety Updates” to mean Periodic Safety Update Reports and objects to this request as duplicative of Request No. 3.

**REQUEST FOR PRODUCTION NO. 5:**

Please produce the electronic Investigational New Drug (“IND”) file for CYMBALTA.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 5:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Moreover, Lilly objects to this request as duplicative of Request No. 1.

**REQUEST FOR PRODUCTION NO. 6:**

Please produce all warning letters sent to YOU from the FDA regarding CYMBALTA.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 6:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which

Plaintiff has access. Lilly also objects to this Request and its use of “warning letters” as vague and ambiguous. Moreover, Lilly objects to this Request as it is not limited to documents relating to any alleged discontinuation-emergent adverse events potentially arising from Cymbalta treatment and therefore seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence. Subject to the foregoing objections, Lilly will direct Plaintiff within its prior production to letters it received from FDA’s Division of Drug Marketing, Advertising, and Communications (“DDMAC”) regarding Cymbalta.

**REQUEST FOR PRODUCTION NO. 7:**

Please produce YOUR responses to all warning letters sent to YOU from the FDA regarding CYMBALTA.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 7:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request and its use of “warning letters” as vague and ambiguous. Moreover, Lilly objects to this Request as it is not limited to documents relating to any alleged discontinuation-emergent adverse events potentially arising from Cymbalta treatment and therefore seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence. Subject to the foregoing objections, Lilly will direct Plaintiff within its prior production to its responses to letters it received from FDA’s Division of Drug Marketing, Advertising, and Communications (“DDMAC”) regarding Cymbalta.

**REQUEST FOR PRODUCTION NO. 8:**

Please produce the transcript of any FDA Advisory Committee meetings regarding CYMBALTA for any indication.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 8:**

Lilly objects to this Request to the extent it seeks publicly available information.

**REQUEST FOR PRODUCTION NO. 9:**

Please produce any DOCUMENTS submitted to the FDA as part of any Advisory Committee meeting related to CYMBALTA.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 9:**

Lilly objects to this Request to the extent it seeks publicly available information.

**REQUEST FOR PRODUCTION NO. 10:**

Please produce any and all Form 483 and/or Warning Letters that YOU received from the FDA related to CYMBALTA.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 10:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request and its use of “Warning Letters” as vague and ambiguous. Lilly further objects to this Request as it is not limited to documents relating to any alleged discontinuation-emergent adverse events potentially arising from Cymbalta treatment and therefore seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence. Moreover, Lilly objects to this request as duplicative of Request No. 6.



**REQUEST FOR PRODUCTION NO. 11:**

Please produce YOUR responses to all Form 483 and/or Warning Letters that YOU received from the FDA related to CYMBALTA.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 11:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request and its use of “Warning Letters” as vague and ambiguous. Lilly further objects to this Request as it is not limited to documents relating to any alleged discontinuation-emergent adverse events potentially arising from Cymbalta treatment and therefore seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence. Moreover, Lilly objects to this request as duplicative of Request No. 7.

**REQUEST FOR PRODUCTION NO. 12:**

Please produce all DOCUMENTS reflecting any settlements, agreements, resolutions, fines, sanctions and/or additional regulatory actions that arose as a result of the Form 483 and/or Warning Letters that YOU received from the FDA related to CYMBALTA.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 12:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request and its use of “Warning Letters” as vague and ambiguous. Lilly further objects Lilly also objects to this Request as it is not limited to documents relating to any alleged discontinuation-emergent adverse events potentially arising from Cymbalta treatment and therefore seeks information that is neither relevant nor likely to

lead to the discovery of admissible evidence. Moreover, Lilly objects to this request as duplicative of Requests Nos. 6 and 7.

**REQUEST FOR PRODUCTION NO. 13:**

Please produce all DOCUMENTS related to any COMMUNICATIONS with the FDA about CYMBALTA containing any of the following terms (or any derivative term): DEAE, withdrawal, discontinuation or discontinuing, dependence, habit-forming, addiction, quitting, tapering, brain zaps, electric shock, down regulation, half-life, missed dose, “greater than or equal to,” Perahia, Rosenbaum, or Schatzberg.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 13:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Those productions include communications between Lilly and FDA about Cymbalta and discontinuation-emergent adverse events, as well as email files from nine Lilly employees who had significant involvement in or responsibility for Cymbalta that were responsive to certain Cymbalta-related and discontinuation-related search terms. To the extent this Request seeks documents beyond those described above, the burden of complying with the Request outweighs Plaintiff’s need for documents of this scope. Lilly also objects to this Request to the extent it is not limited to documents relating to any alleged discontinuation-emergent adverse events potentially arising from Cymbalta treatment and therefore seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence.

**REQUEST FOR PRODUCTION NO. 14:**

Please produce all DOCUMENTS related to any COMMUNICATIONS with the FDA about Prozac or fluoxetine containing any of the following terms (or any derivative term): DEAE, withdrawal, discontinuation or discontinuing, dependence, habit-forming, addiction, quitting, tapering, brain zaps, electric shock, down regulation, half-life, missed dose, “greater than or equal to,” Perahia, Rosenbaum, or Schatzberg.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 14:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request as it is not to limited documents relating to Cymbalta and therefore seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence. The Complaint does not allege that Plaintiff was treated with Prozac, and as such, documents relating to Prozac or fluoxetine are irrelevant in this matter. Subject to the foregoing objections, Lilly will direct Plaintiff within its prior production to documents relating to Prozac and discontinuation symptoms.

**REQUEST FOR PRODUCTION NO. 15:**

Please produce all DOCUMENTS related to any COMMUNICATIONS with the FDA about Zyprexa or olanzapine containing any of the following terms (or any derivative term): DEAE, withdrawal, discontinuation or discontinuing, dependence, habit-forming, addiction, quitting, tapering, brain zaps, electric shock, down regulation, half-life, missed dose, “greater than or equal to,” Perahia, Rosenbaum, or Schatzberg.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 15:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope. Lilly also objects to this Request as it is not limited to documents relating to Cymbalta and therefore seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence. The Complaint does not allege that Plaintiff was treated with Zyprexa, an antipsychotic that is not in the same class of medications as Cymbalta, and as such, documents relating to Zyprexa or olanzapine are irrelevant in this matter.

**REQUEST FOR PRODUCTION NO. 16:**

Please produce all DOCUMENTS reflecting COMMUNICATIONS with the FDA about the section of the US LABEL titled “Discontinuation of Treatment with Cymbalta.”

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 16:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly. Plaintiff has access to Lilly’s Investigational New Drug application and New Drug Application productions in the *Hexum/Herrera* actions, which contain communications between Lilly and FDA about Cymbalta’s United States Package Insert (“U.S. label”), including drafts and mark-ups of the U.S. label.

**REQUEST FOR PRODUCTION NO. 17:**

Please produce all DOCUMENTS reflecting COMMUNICATIONS with the FDA about the sections of the US LABEL titled “Dosage and Administration” or “Medication Administration” or “Information for Patients” (depending on year).

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 17:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly. Plaintiff has access to Lilly's Investigational New Drug application and New Drug Application productions in the *Hexum/Herrera* actions, which contain communications between Lilly and FDA about Cymbalta's U.S. label, including drafts and mark-ups of the U.S. label.

**REQUEST FOR PRODUCTION NO. 18:**

Please produce all DOCUMENTS that reflect COMMUNICATIONS between LILLY and the FDA concerning LILLY's Medical Information Letters, or similar letters, concerning the potential risk of withdrawal or discontinuation from CYMBALTA.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 18:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request and its use of "similar letters" as vague and ambiguous. Medical information letters do not undergo a FDA submission and review process. Subject to the foregoing objections, Lilly with direct Plaintiff within its prior productions to its medical information letters concerning Cymbalta and discontinuation-emergent adverse events.

**REQUEST FOR PRODUCTION NO. 19:**

Please produce all COMMUNICATIONS between YOU and the FDA concerning the half-life of CYMBALTA.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 19:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly. Plaintiff has access to Lilly's Investigational New Drug application and New Drug Application productions in the *Hexum/Herrera* actions, which contain communications between Lilly and FDA about Cymbalta's U.S. label, which includes information about Cymbalta's half-life.

**REQUEST FOR PRODUCTION NO. 20:**

Please produce all COMMUNICATIONS between YOU and the FDA concerning the enteric coating of CYMBALTA.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 20:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly. Plaintiff has access to Lilly's Investigational New Drug application and New Drug Application productions in the *Hexum/Herrera* actions, which contain communications between Lilly and FDA about Cymbalta's U.S. label, which includes information and warnings about Cymbalta's enteric coating.

**REQUEST FOR PRODUCTION NO. 21:**

Please produce a copy of each FDA-approved version of the package insert for CYMBALTA used by LILLY since it began marketing CYMBALTA in the United States.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 21:**

Lilly objects to this Request as overly broad and unduly burdensome to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access.

**REQUEST FOR PRODUCTION NO. 22:**

Please produce a copy of each version of the LABEL for CYMBALTA in each foreign country wherein CYMBALTA was approved for marketing in that country.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 22:**

Lilly objects to this Request as overly broad and unduly burdensome to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access or documents that are publicly available. The Complaint alleged that Plaintiff was treated with Cymbalta in the United States based on labeling information that was approved by the FDA, and to the extent that this Request seeks labeling information approved by foreign regulatory bodies outside the United States, these documents are not relevant nor likely to lead to the discovery of admissible evidence.

**REQUEST FOR PRODUCTION NO. 23:**

Please produce the electronic Adverse Event Reporting database for CYMBALTA.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 23:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request as it is not limited to documents relating to any alleged discontinuation-emergent adverse events potentially arising from Cymbalta treatment and therefore seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence. Lilly further objects to this Request to this extent that it seeks personal health information protected under HIPAA and other privacy laws. Moreover, Lilly's database for adverse events is accessible only using specialized software, and Lilly objects to this

Request as unduly burdensome to the extent it seeks contents of this database in its native format. Subject to the foregoing objections, Lilly will direct Plaintiff within its prior productions to Cymbalta adverse event data that have been produced in Excel format.

## **II. INTERNAL COMMUNICATIONS ABOUT CYMBALTA**

### **REQUEST FOR PRODUCTION NO. 24:**

Please produce all DOCUMENTS reflecting LILLY's internal COMMUNICATIONS and/or deliberations concerning the section of the US CYMBALTA LABEL titled "Discontinuation of Treatment with Cymbalta," including not limited to all emails, memorandums, drafts, comments, edits, redlines, or discussions about those edits of those sections of the US CYMBALTA LABEL.

### **OBJECTIONS TO REQUEST FOR PRODUCTION NO. 24:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request and its use of "deliberations" and "discussions" as vague and ambiguous. Lilly has searched the email files of nine Lilly employees who had significant involvement in or responsibility for Cymbalta and produced documents that were responsive to certain Cymbalta-related and discontinuation-related search terms. Plaintiff has access to those documents. To the extent that this Request for "all DOCUMENTS" requires Lilly to expand its efforts to a company-wide search, the burden of complying with the Request outweighs Plaintiff's need for documents of this scope.



**REQUEST FOR PRODUCTION NO. 25:**

Please produce all DOCUMENTS reflecting LILLY's internal COMMUNICATIONS and/or deliberations concerning the section of the US CYMBALTA LABEL titled "Dosage and Administration" or "Medication Administration" or "Information for Patients" (depending on year), including not limited to all emails, memorandums, drafts, comments, edits, redlines, or discussions about those edits of the that section of the US CYMBALTA LABEL.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 25:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request and its use of "deliberations" and "discussions" as vague and ambiguous. Lilly has searched the email files of nine Lilly employees who had significant involvement in or responsibility for Cymbalta and produced documents that were responsive to certain Cymbalta-related and discontinuation-related search terms. Plaintiff has access to those documents. To the extent that this Request for "all DOCUMENTS" requires Lilly to expand its efforts to a company-wide search, the burden of complying with the Request outweighs Plaintiff's need for documents of this scope.

**REQUEST FOR PRODUCTION NO. 26:**

Please produce all DOCUMENTS reflecting LILLY's internal COMMUNICATIONS and/or deliberations concerning the following sentences in the US CYMBALTA LABEL as it was approved in 2004, including but not limited to all emails, memorandums, drafts, comments, edits, redlines, or discussions about those edits: "Duloxetine should be swallowed whole and should not be chewed or crushed, nor should the contents be sprinkled on food or mixed with liquids. All of these might affect the enteric coating."

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 26:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request and its use of “deliberations” and “discussions” as vague and ambiguous. Lilly has searched the email files of nine Lilly employees who had significant involvement in or responsibility for Cymbalta and produced documents that were responsive to certain Cymbalta-related and discontinuation-related search terms. Plaintiff has access to those documents. To the extent that this Request for “all DOCUMENTS” requires Lilly to expand its efforts to a company-wide search, the burden of complying with the Request outweighs Plaintiff’s need for documents of this scope.

**REQUEST FOR PRODUCTION NO. 27:**

Please produce all DOCUMENTS that reflect LILLY’s reason for changing the US LABEL concerning “Discontinuation of Treatment with Cymbalta” in 2008 from “the following symptoms occurred at a rate greater than or equal to 2%” to “the following symptoms occurred at a rate greater than or equal to 1%.”

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 27:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly has searched the email files of nine Lilly employees who had significant involvement in or responsibility for Cymbalta and produced documents that were responsive to certain Cymbalta-related and discontinuation-related search terms. Lilly’s prior productions also include communications between Lilly and FDA about changes to the language in Cymbalta’s U.S. label. Plaintiff has access to those documents. To the extent that this

Request for “all DOCUMENTS” requires Lilly to expand its efforts to a company-wide search, the burden of complying with the Request outweighs Plaintiff’s need for documents of this scope.

**REQUEST FOR PRODUCTION NO. 28:**

Please produce all DOCUMENTS that reflect LILLY’s reason for adding to the 2009 US CYMBALTA LABEL “or tapered” in the context of “Following abrupt ... discontinuation ...” in the section titled “Discontinuation of Treatment with Cymbalta.”

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 28:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly has searched the email files of nine Lilly employees who had significant involvement in or responsibility for Cymbalta and produced documents that were responsive to certain Cymbalta-related and discontinuation-related search terms. Lilly’s prior productions also include communications between Lilly and FDA about changes to the language in Cymbalta’s U.S. label. Plaintiff has access to those documents. To the extent that this Request for “all DOCUMENTS” requires Lilly to expand its efforts to a company-wide search, the burden of complying with the Request outweighs Plaintiff’s need for documents of this scope.

**REQUEST FOR PRODUCTION NO. 29:**

Please produce all DOCUMENTS that reflect LILLY’s reason for changing the US CYMBALTA LABEL in 2012 from “the following symptoms occurred at a rate greater than or equal to 1%” to “at 1% or greater” in the section titled “Discontinuation of Treatment with Cymbalta.”

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 29:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly has searched the email files of nine Lilly employees who had significant involvement in or responsibility for Cymbalta and produced documents that were responsive to certain Cymbalta-related and discontinuation-related search terms. Lilly's prior productions also include communications between Lilly and FDA about changes to the language in Cymbalta's U.S. label. Plaintiff has access to those documents. To the extent that this Request for "all DOCUMENTS" requires Lilly to expand its efforts to a company-wide search, the burden of complying with the Request outweighs Plaintiff's need for documents of this scope.

**REQUEST FOR PRODUCTION NO. 30:**

Please produce all DOCUMENTS that reflect LILLY's reason for creating CYMBALTA as capsules containing enteric-coated pellets of duloxetine hydrochloride.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 30:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request to the extent that it seeks documents concerning Cymbalta's design or manufacture that are not limited to documents about any alleged discontinuation-emergent adverse events potentially arising from Cymbalta treatment and therefore seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence.

**REQUEST FOR PRODUCTION NO. 31:**

Please produce all DOCUMENTS reflecting LILLY's internal COMMUNICATIONS and/or deliberations concerning the design of CYMBALTA as enteric-coated pellets contained within a capsule.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 31:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request and its use of "deliberations" as vague and ambiguous. Lilly further objects to this Request to the extent that it seeks documents concerning Cymbalta's design or manufacture that are not limited to documents about any alleged discontinuation-emergent adverse events potentially arising from Cymbalta treatment and therefore seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence. Moreover, Lilly objects to this request as duplicative of Request No. 30.

**REQUEST FOR PRODUCTION NO. 32:**

Please produce all DOCUMENTS reflecting LILLY's internal COMMUNICATIONS and/or deliberations concerning the development of a dosage of CYMBALTA below 20mg.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 32:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request and its use of "deliberations" as vague and ambiguous. Lilly further objects to this Request to the extent that it seeks documents concerning development of Cymbalta's dosages that are not limited to documents about any alleged discontinuation-emergent adverse events potentially arising from Cymbalta treatment and

therefore seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence.

**REQUEST FOR PRODUCTION NO. 33:**

Please produce all DOCUMENTS reflecting LILLY's internal COMMUNICATIONS and/or deliberations concerning the development of CYMBALTA as a scored tablet.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 33:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request and its use of "deliberations" as vague and ambiguous. Lilly further objects to this Request to the extent that it seeks documents concerning Cymbalta's design or manufacture that are not limited to documents about any alleged discontinuation-emergent adverse events potentially arising from Cymbalta treatment and therefore seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence. Moreover, Lilly objects to this request as duplicative of Request Nos. 30 and 31.

**REQUEST FOR PRODUCTION NO. 34:**

Please produce all memoranda, presentations, and/or reports, whether prepared internally or provided to LILLY by a third-party, that discuss, in any way, CYMBALTA and WITHDRAWAL.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 34:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which

Plaintiff has access. Lilly has searched the email files of nine Lilly employees who had significant involvement in or responsibility for Cymbalta and produced documents that were responsive to certain Cymbalta-related and discontinuation-related search terms. Lilly's prior productions also include communications between Lilly and FDA including reports that discuss discontinuation-emergent adverse events. Plaintiff has access to those documents. To the extent that this Request for "all DOCUMENTS" requires Lilly to expand its efforts to a company-wide search, the burden of complying with the Request outweighs Plaintiff's need for documents of this scope.

**REQUEST FOR PRODUCTION NO. 35:**

Please produce all electronic mail ("email") for the individuals identified in Interrogatory Nos. 1 & 3, whether internal or external and whether on LILLY's current computer operating system, on individual employees' laptop computers, or archive systems, which contain at least one of the following terms:

**Cy!, dulo!, Aricclaim, Xeristar, Yentreve, Duzela, Dulane, Cymgen, Prozac, Fluox!, Paxil, Parox!, Zolof!, Sertra!, Celexa, Citalop!, Lexapro, Escitalop!, Effexor, venlafa!, Pristiq, desvenlafax!, milnacipr!, levomilnacipr!, SSRI!, SNRI!, or anti!,**

*and* at least one of the following terms:

**DEAE!, discon!, withd!, taper!, cold w/1turkey, addict!, habit!, paresth!, zap!, electric w/4 shock, dizz!, Rosenbaum, Schatzberg, Glenmullen, half-life, "missed dose," downregu!, "greater than or equal to," Perahia, enteric, pellets, "delayed release."**

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 35:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which

Plaintiff has access. Lilly also objects to this Request as not limited to documents relating to Cymbalta or any alleged discontinuation-emergent adverse events potentially arising from Cymbalta treatment. Lilly further objects to terms such as “anti!”, “addict!”, “habit!”, “greater than or equal to”, or “delayed release” as overly broad and far beyond the scope of the allegations of the Complaint. Lilly has searched the email files of nine Lilly employees who had significant involvement in or responsibility for Cymbalta and produced documents that were responsive to certain Cymbalta-related and discontinuation-related search terms, including many of the terms contained in this Request. Plaintiff has access to those documents. To the extent that this Request seeks documents beyond those described above, the burden of complying with the Request outweighs Plaintiff’s need for documents of this scope.

**REQUEST FOR PRODUCTION NO. 36:**

Please produce all DOCUMENTS that reflect LILLY’s internal COMMUNICATIONS and/or deliberations concerning any and all letters used by LILLY to respond to inquiries regarding CYMBALTA and DEAEs, discontinuation, withdrawal, dependence, or addiction.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 36:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request and its use of “deliberations” as vague and ambiguous. Lilly has searched the email files of nine Lilly employees who had significant involvement in or responsibility for Cymbalta and produced documents that were responsive to certain Cymbalta-related and discontinuation-related search terms. Lilly has also produced its medical information letters used to respond to inquiries from medical professionals about Cymbalta and discontinuation. Plaintiff has access to those documents. To the extent that this



Request for “all DOCUMENTS” requires Lilly to expand its efforts to a company-wide search, the burden of complying with the Request outweighs Plaintiff’s need for documents of this scope.

**REQUEST FOR PRODUCTION NO. 37:**

Please produce all DOCUMENTS that reflect LILLY’s internal COMMUNICATIONS and/or deliberations concerning any of LILLY’s Medical Information Letters, or similar letters, concerning the potential risk of withdrawal or discontinuation from CYMBALTA.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 37:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request and its use of “deliberations” and “similar letters” as vague and ambiguous. Lilly has searched the email files of nine Lilly employees who had significant involvement in or responsibility for Cymbalta and produced documents that were responsive to certain Cymbalta-related and discontinuation-related search terms. Lilly has also produced its medical information letters used to respond to inquiries from medical professionals about Cymbalta and discontinuation. Plaintiff has access to those documents. To the extent that this Request for “all DOCUMENTS” requires Lilly to expand its efforts to a company-wide search, the burden of complying with the Request outweighs Plaintiff’s need for documents of this scope. Moreover, Lilly objects to this request as duplicative of Request No. 36.

**REQUEST FOR PRODUCTION NO. 38:**

Please produce all minutes of meetings of any LILLY committee, working group, department, board, etc. where CYMBALTA and WITHDRAWAL were discussed.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 38:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly has searched the email files of nine Lilly employees who had significant involvement in or responsibility for Cymbalta and produced documents that were responsive to certain Cymbalta-related and discontinuation-related search terms, including any responsive meeting minutes. Plaintiff has access to those documents. To the extent that this Request for “all minutes of meetings” requires Lilly to expand its efforts to a company-wide search, the burden of complying with the Request outweighs Plaintiff’s need for documents of this scope.

**REQUEST FOR PRODUCTION NO. 39:**

Please produce all DOCUMENTS that reflect LILLY’s internal COMMUNICATIONS and/or deliberations concerning why the rate of WITHDRAWAL reflected in the PERAHIA article was not included in the US LABEL.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 39:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request and its use of “deliberations” as vague and ambiguous. Lilly has searched the email files of nine Lilly employees who had significant involvement in or responsibility for Cymbalta, including Dr. David Perahia, and produced documents that were responsive to certain Cymbalta-related and discontinuation-related search terms. Plaintiff has access to those documents. To the extent that this Request for “all

DOCUMENTS” requires Lilly to expand its efforts to a company-wide search, the burden of complying with the Request outweighs Plaintiff’s need for documents of this scope.

**REQUEST FOR PRODUCTION NO. 40:**

Please produce all DOCUMENTS that reflect LILLY’s internal COMMUNICATIONS and/or deliberations concerning why the rate of WITHDRAWAL reflected in the PERAHIA article was included in the European LABEL.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 40:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request and its use of “deliberations” as vague and ambiguous. Lilly has searched the email files of nine Lilly employees who had significant involvement in or responsibility for Cymbalta, including Dr. David Perahia, and produced documents that were responsive to certain Cymbalta-related and discontinuation-related search terms. Plaintiff has access to those documents. To the extent that this Request for “all DOCUMENTS” requires Lilly to expand its efforts to a company-wide search, the burden of complying with the Request outweighs Plaintiff’s need for documents of this scope. Subject to the foregoing, Lilly will direct Plaintiff within its prior productions to documents concerning the European Medicines Agency’s request for the inclusion in the European labels for SSRIs and SNRIs of the aggregate rate of discontinuation-emergent adverse events from clinical trials.

**REQUEST FOR PRODUCTION NO. 41:**

Please produce all DOCUMENTS that reflect LILLY’s internal COMMUNICATIONS concerning discontinuation or withdrawal symptoms upon discontinuation of Effexor, including

but not limited to any discussion concerning the language contained in the US Effexor LABEL concerning WITHDRAWAL.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 41:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope. Lilly also objects to this Request as it is not limited to documents relating to Cymbalta and therefore seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence. A third party, not Lilly, manufactures Effexor, and the Complaint does not allege that Plaintiff was treated with Effexor. As such, documents relating to Effexor or venlafaxine are irrelevant in this matter and not likely to lead to the discovery of admissible evidence.

**III. COMMUNICATIONS WITH MEDICAL PROFESSIONALS**  
**REQUEST FOR PRODUCTION NO. 42:**

Please produce any “Dear Healthcare Professional” or similar letters to doctors, pharmacies or other groups, organizations about CYMBALTA.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 42:**

Lilly objects to this Request as overly broad and unduly burdensome to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request and its use of “similar letters”, “groups”, and “organizations” as vague and ambiguous. Subject to the foregoing objections, Lilly will direct Plaintiff within its prior productions to any Dear Healthcare Professional letters.

**REQUEST FOR PRODUCTION NO. 43:**

Please produce all DOCUMENTS that contain a record or description of COMMUNICATIONS to LILLY from MEDICAL PROFESSIONALS or the public, including but not limited to call logs, inquiring about CYMBALTA that mention DEAEs, withdrawal, discontinuation or discontinuing, dependence, habit-forming, addiction, quitting, tapering, brain zaps, electric shock, down regulation, half-life (or any related or derivative terms).

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 43:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Those productions include records of inquiries from medical professionals concerning Cymbalta and discontinuation.

**REQUEST FOR PRODUCTION NO. 44:**

Please produce any and all letters used by LILLY to respond to inquiries regarding CYMBALTA and DEAEs, discontinuation, withdrawal, dependence, or addiction.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 44:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Subject to the foregoing objections, Lilly will direct Plaintiff within its prior productions to its medical information letters concerning Cymbalta and discontinuation.

**REQUEST FOR PRODUCTION NO. 45:**

Please produce a copy of each and every version of LILLY's "Medical Information Letter" or similar letters to doctors, pharmacies or other groups, organizations or entities discussing the potential risk of withdrawal or discontinuation from CYMBALTA.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 45:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request and its use of "similar letters", "groups", and "organizations" as vague and ambiguous. Lilly further objects to this Request as duplicative of Request No. 44.

**REQUEST FOR PRODUCTION NO. 46:**

Please produce all DOCUMENTS that identify MEDICAL PROFESSIONALS to whom LILLY sent a Medical Information Letter concerning the potential risk of withdrawal or discontinuation from CYMBALTA (e.g., an Excel spreadsheet or Access spreadsheet).

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 46:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and subject matter. Lilly also objects to this Request as it is not limited to information about medical professionals who treated Plaintiff and therefore seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence. Only certain physicians treated Plaintiff, and documents concerning other medical professionals to whom Lilly sent medical information letters are irrelevant to this matter and not likely to lead to the discovery of admissible evidence.

**REQUEST FOR PRODUCTION NO. 47:**

Please produce any and all DOCUMENTS that reflect each inquiry from a MEDICAL PROFESSIONAL concerning Cymbalta and withdrawal or discontinuation, including but not limited to written letters, telephone calls, online requests, sales representative relay.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 47:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Those productions include records of inquiries from medical professionals concerning Cymbalta and discontinuation. Lilly also objects to this Request as duplicative of Request No. 43.

**IV. MEDICAL LITERATURE AND CONTINUING MEDICAL EDUCATION**  
**REQUEST FOR PRODUCTION NO. 48:**

Please produce all publication plans for CYMBALTA, whether prepared internally or by a third-party.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 48:**

Lilly objects to this Request as overly broad as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request as it is not limited to documents relating to alleged discontinuation-emergent adverse events potentially arising from Cymbalta treatment and therefore seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence. Plaintiff is aware of the publications involving Cymbalta that relate to the discontinuation symptoms that are the focus of this lawsuit.

**REQUEST FOR PRODUCTION NO. 49:**

Please produce all DOCUMENTS reflecting LILLY's involvement in the drafting, editing, and publication the PERAHIA ARTICLE, including but not limited to all email communications, article drafts, and publication plans relating to the PERAHIA ARTICLE.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 49:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Those productions include a copy of the PERAHIA ARTICLE and documents from Dr. David Perahia's email files that were responsive to certain Cymbalta-related and discontinuation-related search terms. To the extent that this Request for "all DOCUMENTS" requires Lilly to expand its efforts to a company-wide search, the burden of complying with the Request outweighs Plaintiff's need for documents of this scope. Lilly also objects to the Request to the extent it is duplicative of Request No. 48.

**REQUEST FOR PRODUCTION NO. 50:**

Please produce the study protocol and final study reports for each of the CYMBALTA trials discussed in the PERAHIA ARTICLE.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 50:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Subject to the foregoing objections, Lilly will direct Plaintiff within its production to the study protocols and final study reports for each trial discussed in the PERAHIA ARTICLE.



**REQUEST FOR PRODUCTION NO. 51:**

Please produce the raw data, including but not limited to the case report forms for each of the CYMBALTA trials discussed in the PERAHIA ARTICLE.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 51:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope. Lilly further objects to this Request to this extent that it seeks personal health information protected under HIPAA and other privacy laws. Production of raw data and case report forms requires labor intensive review of voluminous files in order to screen out or redact confidential patient information. Lilly has produced the PERAHIA ARTICLE, documents from Dr. David Perahia's email files that were responsive to certain Cymbalta-related and discontinuation-related search terms, and all Cymbalta study protocols and final study reports that could be located through a reasonably diligent search, including those from the nine trials discussed in the PERAHIA ARTICLE. Plaintiff has access to those documents, which aggregate and summarize raw data and information contained in the case report forms. To the extent that Plaintiff seeks documents beyond those described above, the burden of complying with the Request outweighs Plaintiff's need for documents of this scope.

**REQUEST FOR PRODUCTION NO. 52:**

Please produce all DOCUMENTS reflecting the amount of compensation given to the authors of the PERAHIA ARTICLE, including but not limited to non-listed authors in the final publication.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 52:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope. Lilly also objects to this Request and its use of "compensation" and "non-listed authors"

as vague and ambiguous. Lilly further objects to this Request on behalf of Dr. David Perahia who opposes disclosure of his compensation on privacy grounds. *See Hexum/Herrera* actions, Deposition of David Perahia, Dec. 12, 2014, at 26:18-28:13.

**REQUEST FOR PRODUCTION NO. 53:**

Please produce a copy of the articles identified in Interrogatories Nos. 18 & 19.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 53:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope. Lilly refers Plaintiff to its objections to Interrogatories Nos. 18 and 19. To the extent that Lilly provides citations for the journal publications requested in Interrogatories Nos. 18 and 19, Lilly further objects to this Request as those articles are available to Plaintiff in the public domain.

**REQUEST FOR PRODUCTION NO. 54:**

Please produce all DOCUMENTS reflecting LILLY's involvement in the drafting, editing, and publication of those articles identified in Interrogatories Nos. 18 & 19.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 54:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also refers Plaintiff to its objections to Interrogatories Nos. 18 and 19. To the extent that Lilly provides citations for the journal publications requested in Interrogatories Nos. 18 and 19, those articles contain disclosure statements concerning Lilly's sponsorship. To the extent that this Request for "all DOCUMENTS" requires Lilly to expand its efforts to a company-wide search, the burden of complying with the Request outweighs Plaintiff's need for

documents of this scope. Lilly also objects to the Request to the extent it is duplicative of Request Nos. 48 and 49.

**REQUEST FOR PRODUCTION NO. 55:**

Please produce all DOCUMENTS reflecting the amount of compensation given to the authors of those articles identified in Interrogatories Nos. 18 &19, including but not limited to compensation associated with the article's publication. In lieu of producing these documents, Plaintiff would accept an Excel chart listing each author and the total amount of compensation received by that author by LILLY, by year.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 55:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request and its use of "compensation" as vague and ambiguous. Lilly also refers Plaintiff to its objections to Interrogatories Nos. 18 and 19. Lilly further objects to this Request to the extent it is duplicative of Request No. 52.

**REQUEST FOR PRODUCTION NO. 56:**

Please produce all DOCUMENTS reflecting any communications between LILLY and the authors of the articles identified in Interrogatories Nos. 18 &19 concerning discontinuation or withdrawal symptoms upon discontinuation of any SSRI or SNRI, including but not limited to CYMBALTA, Effexor, Prozac, Paxil and Zoloft.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 56:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which

Plaintiff has access. Lilly also objects to this Request as not limited to documents concerning Cymbalta. The Complaint does not allege that Plaintiff was treated with Effexor, Prozac, Paxil or Zoloft, and third parties, not Lilly, manufacture Effexor, Paxil, and Zoloft. As such, documents relating to Effexor, Prozac, Paxil, and Zoloft are irrelevant in this matter. Lilly also refers Plaintiff to its objections to Interrogatories Nos. 18 and 19. To the extent that this Request for “all DOCUMENTS” requires Lilly to expand its efforts to a company-wide search, the burden of complying with the Request outweighs Plaintiff’s need for documents of this scope. Lilly further objects to this Request to the extent it is duplicative of Request Nos. 48, 49, 54, and 55.

**REQUEST FOR PRODUCTION NO. 57:**

Please produce all DOCUMENTS reflecting any COMMUNICATIONS between LILLY and Mario Fava concerning discontinuation or withdrawal symptoms upon discontinuation of any SSRI or SNRI, including but not limited to CYMBALTA, Effexor, Prozac, Paxil and Zoloft.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 57:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents in the possession of third parties. Lilly also objects to this Request as not limited to documents relating to Cymbalta. Dr. Maurizio Fava is not a current or former Lilly employee. The Complaint does not allege that Plaintiff was treated with Effexor, Prozac, Paxil, or Zoloft, and third parties, not Lilly, manufacture Effexor, Paxil, and Zoloft. As such, this Request seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence. Moreover, Lilly objects to this Request to the extent Plaintiff already has or may obtain access to Dr. Fava’s third-party production in the *Hexum/Herrera* actions.

**REQUEST FOR PRODUCTION NO. 58:**

Please produce all DOCUMENTS reflecting any COMMUNICATIONS between LILLY and Jerrold Rosenbaum concerning discontinuation or withdrawal symptoms upon discontinuation of any SSRI or SNRI, including but not limited to CYMBALTA, Effexor, Prozac, Paxil and Zoloft.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 58:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents in the possession of third parties. Lilly also objects to this Request as not limited to documents relating to Cymbalta. Dr. Jerrold Rosenbaum is not a current or former Lilly employee. The Complaint does not allege that Plaintiff was treated with Effexor, Prozac, Paxil, or Zoloft, and third parties, not Lilly, manufacture Effexor, Paxil, and Zoloft. As such, this Request seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence. Moreover, Lilly objects to this Request to the extent Plaintiff already has or may obtain access to Dr. Rosenbaum's third-party production in the *Hexum/Herrera* actions.

**REQUEST FOR PRODUCTION NO. 59:**

Please produce all DOCUMENTS reflecting any COMMUNICATIONS between LILLY and Peter Haddad concerning discontinuation or withdrawal symptoms upon discontinuation of any SSRI or SNRI, including but not limited to CYMBALTA, Effexor, Prozac, Paxil and Zoloft.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 59:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents in the possession of third parties or previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request as not

limited to documents relating to Cymbalta. Dr. Peter Haddad is not a current or former Lilly employee. The Complaint does not allege that Plaintiff was treated with Effexor, Prozac, Paxil, or Zoloft, and third parties, not Lilly, manufacture Effexor, Paxil, and Zoloft. As such, this Request seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence. During his work with Lilly, Dr. Haddad communicated principally with Dr. Perahia, whose emails that are responsive to certain Cymbalta-related and discontinuation-related search terms have been produced by Lilly. Plaintiff has access to those documents.

**REQUEST FOR PRODUCTION NO. 60:**

Please produce all DOCUMENTS reflecting any communications between LILLY and Alan Schatzberg concerning discontinuation or withdrawal symptoms upon discontinuation of any SSRI or SNRI, including but not limited to CYMBALTA, Effexor, Prozac, Paxil and Zoloft.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 60:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents in the possession of third parties. Lilly also objects to this Request as not limited to documents relating to Cymbalta. Dr. Alan Schatzberg is not a current or former Lilly employee. The Complaint does not allege that Plaintiff was treated with Effexor, Prozac, Paxil, or Zoloft, and third parties, not Lilly, manufacture Effexor, Paxil, and Zoloft. As such, this Request seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence.

**REQUEST FOR PRODUCTION NO. 61:**

Please produce all CYMBALTA clinical trials wherein DEAEs or withdrawal symptoms were measured, noted, calculated, or where data concerning DEAEs or withdrawal was obtained,

regardless of whether measuring DEAEs or withdrawal symptoms was part of the trial's original protocol. Please note this request is not limited in time (i.e., pre-approval or post-approval), geography (i.e., location of the study or clinical trial), type (i.e., placebo-controlled, active-controlled, or open), authorship (i.e., LILLY-sponsored or conducted by a third-party), or whether the trial was FDA-sanctioned. This request seeks all DEAE or withdrawal clinical data within LILLY's possession.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 61:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents in the possession of third parties or previously produced by Lilly in productions to which Plaintiff has access. Lilly has produced all Lilly-sponsored clinical trials relating to Cymbalta that were located through a reasonably diligent search of the documents within its possession, custody, and control. Plaintiff has access to these documents.

**REQUEST FOR PRODUCTION NO. 62:**

Please produce any presentations, PowerPoint presentations, memoranda, product brochures / marketing materials, and/or audio/video recordings, used by LILLY with regard to CYMBALTA that mention the potential risk of withdrawal or discontinuation from CYMBALTA.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 62:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly has produced email files from nine Lilly employees who had significant involvement in or responsibility for Cymbalta that were responsive to certain Cymbalta-related and discontinuation-related search terms. Lilly has also produced its Form

2253 submissions containing Cymbalta marketing materials and advertisements. Those productions contain numerous examples of PowerPoint presentations, memoranda, promotional materials, and other materials concerning Cymbalta. To the extent this request requires a company-wide search for additional materials, the burden of complying with this Request outweighs Plaintiff's need for documents of this scope.

**REQUEST FOR PRODUCTION NO. 63:**

Please produce all Continuing Medical Education ("CME") presentations or programs, including those DOCUMENTS given to attendees of CMEs, sponsored or created by YOU that mention DEAEs, withdrawal, discontinuation, dependence or addiction, whether related to CYMBALTA or not, including but not limited to presentations that reference Prozac / fluoxetine and/or Effexor / venlafaxine.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 63:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request as it is not limited to documents relating to Cymbalta and therefore seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence. The Complaint does not allege that Plaintiff was treated with Prozac or Effexor, and a third party, not Lilly, manufactures Effexor. As such, documents relating to Prozac/fluoxetine or Effexor/venlafaxine are irrelevant in this matter. Furthermore, Lilly has already produced materials responsive to this request, including some Prozac-related CME materials, and Plaintiff has access to those documents. Finally, Lilly objects to this Request to the extent it is duplicative of Request No. 62.



**REQUEST FOR PRODUCTION NO. 64:**

Please produce DOCUMENTS which list, in whatever interval those lists were compiled, key opinion leaders / thought leaders related to CYMBALTA.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 64:**

Lilly objects to this Request as overly broad as to time and refers Plaintiff to its objections to Interrogatory No. 4.

**REQUEST FOR PRODUCTION NO. 65:**

Please produce all DOCUMENTS reflecting any agreement with a key opinion leader / thought leader related to CYMBALTA.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 65:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and further objects to the term “agreement” as vague and ambiguous. Any contract with a key opinion leader or thought leader is irrelevant to the allegations of the Complaint and not likely to lead to the discovery of admissible evidence.

**REQUEST FOR PRODUCTION NO. 66:**

Please produce all DOCUMENTS reflecting any compensation given to a key opinion leader / thought leader related to CYMBALTA.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 66:**

Lilly objects to this Request as overly broad as to time and refers Plaintiff to its objections to Interrogatory No. 5.

**V. SALES AND MARKETING**

**REQUEST FOR PRODUCTION NO. 67:**

Please produce all television commercials for CYMBALTA.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 67:**

Lilly objects to this Request as overly broad as to time and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Those productions include transcripts and stills of television commercials for Cymbalta.

**REQUEST FOR PRODUCTION NO. 68:**

Please produce all radio commercials for CYMBALTA.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 68:**

Lilly objects to this Request as overly broad as to time and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Those productions include transcripts of radio commercials for Cymbalta.

**REQUEST FOR PRODUCTION NO. 69:**

Please produce all advertisements in magazines for CYMBALTA.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 69:**

Lilly objects to this Request as overly broad as to time and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Those productions include English-language magazine advertisements for Cymbalta.

**REQUEST FOR PRODUCTION NO. 70:**

Please produce all advertisements on the internet for CYMBALTA.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 70:**

Lilly objects to this Request as overly broad as to time and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access.

**REQUEST FOR PRODUCTION NO. 71:**

Please produce all press releases ever issued by LILLY with regard to CYMBALTA.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 71:**

Lilly objects to this Request as overly broad as to time and scope and to the extent it is not limited to documents relating to any alleged discontinuation-emergent adverse events potentially arising from Cymbalta treatment. Lilly also objects to this Request to the extent it seeks documents that are publicly available.

**REQUEST FOR PRODUCTION NO. 72:**

Please produce all COMMUNICATIONS with WebMD regarding CYMBALTA.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 72:**

Lilly objects to this Request as overly broad as to subject matter. The Complaint contains no mention of WebMD, and this request therefore seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence.

**REQUEST FOR PRODUCTION NO. 73:**

Please produce every marketing plan, including all drafts, for CYMBALTA, regardless of whether that plan was prepared internally or by a third-party.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 73:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Subject to the foregoing objections, Lilly will direct Plaintiff within its prior production to its annual brand plans concerning Cymbalta.

**REQUEST FOR PRODUCTION NO. 74:**

Please produce any report or DOCUMENT reflecting the effectiveness of LILLY's marketing campaigns for CYMBALTA.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 74:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request and its use of "reflecting the effectiveness of Lilly's marketing campaign" as vague and ambiguous and to the extent it seeks documents that are of limited relevance to Plaintiff's treatment. Lilly further objects to this Request to the extent that it is duplicative of Request No. 73 and refers Plaintiff to its objections to Request No. 73.

**REQUEST FOR PRODUCTION NO. 75:**

Please produce every business plan, including all drafts, for CYMBALTA, regardless of whether that plan was prepared internally or by a third-party.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 75:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which

Plaintiff has access. Lilly also objects to this Request to the extent that it is duplicative of Request No. 73 and refers Plaintiff to its objections to Request No. 73

**REQUEST FOR PRODUCTION NO. 76:**

Please produce every launch plan, including all drafts, for CYMBALTA, regardless of whether that plan was prepared internally or by a third-party.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 76:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Plaintiff's treatment with Cymbalta began in 2012, more than seven years after the launch of Cymbalta, and Lilly objects to this Request to the extent that it seeks documents remote in time and of limited relevance to Plaintiff's treatment. Lilly further objects to this Request to the extent that it is duplicative of Request No. 73 and refers Plaintiff to its objections to Request No. 73.

**REQUEST FOR PRODUCTION NO. 77:**

Please produce all COMMUNICATIONS between LILLY and any third-party marketing company or consultant concerning CYMBALTA's direct-to-consumer marketing that discusses, in any way, WITHDRAWAL.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 77:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope. Plaintiff has produced submissions to FDA concerning Cymbalta direct-to-consumer marketing, annual brand plans concerning Cymbalta marketing strategy, Cymbalta advertisements and promotional materials, and other related communications to the extent

captured in the emails of nine Lilly employees responsive to certain Cymbalta-related and discontinuation-related search terms. Plaintiff has access to those documents. To the extent this request requires Lilly to additionally produce “all COMMUNICATIONS between Lilly and any third-party” covering those same topics, the burden of complying with this Request outweighs Plaintiff’s need for documents of this scope.

**REQUEST FOR PRODUCTION NO. 78:**

Please produce all COMMUNICATIONS between LILLY and any third-party marketing company or consultant concerning CYMBALTA’s direct-to-consumer marketing that discusses, in any way, once-a-day versus twice-a-day dosing.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 78:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope. Plaintiff has produced submissions to FDA concerning Cymbalta direct-to-consumer marketing, annual brand plans concerning Cymbalta marketing strategy, Cymbalta advertisements and promotional materials, and other related communications to the extent captured in the emails of nine Lilly employees responsive to certain Cymbalta-related and discontinuation-related search terms. Plaintiff has access to those documents. To the extent this request requires Lilly to additionally produce “all COMMUNICATIONS between Lilly and any third-party” covering those same topics, the burden of complying with this Request outweighs Plaintiff’s need for documents of this scope. Moreover, Lilly objects to this request to the extent that it is duplicative of Request No. 77.

**REQUEST FOR PRODUCTION NO. 79:**

Please produce all DOCUMENTS reflecting any contract or agreement between LILLY and a third-party company or consultant related to CYMBALTA's direct-to-consumer marketing.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 79:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and further objects to the term "agreement" as vague and ambiguous. Any contract with a third-party company or consultant is irrelevant to the allegations of the Complaint and Lilly therefore objects to this Request as not likely to lead to the discovery of admissible evidence.

**REQUEST FOR PRODUCTION NO. 80:**

Please produce all market surveys and focus group results / summaries for CYMBALTA.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 80:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request as it is not limited to documents relating to any alleged discontinuation-emergent adverse events potentially arising from Cymbalta treatment therefore seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence.

**REQUEST FOR PRODUCTION NO. 81:**

Please produce all versions of materials and DOCUMENTS, including but not limited to videos or audio recordings, used to train LILLY pharmaceutical representatives about CYMBALTA.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 81:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Subject to the foregoing objections, Lilly will direct Plaintiff within its prior productions to its sales training modules and standard operating procedures (“SOPs”) for pharmaceutical representatives on Cymbalta and discontinuation.

**REQUEST FOR PRODUCTION NO. 82:**

Please produce DOCUMENTS reflecting LILLY’s policies and practices regarding communicating with a MEDICAL PROFESSIONAL by a LILLY pharmaceutical representative.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 82:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request as not limited to documents relating to Cymbalta. Subject to the foregoing objections, Lilly will direct Plaintiff within its prior productions to Lilly’s SOPs on pharmaceutical representatives’ communication with medical professionals.

**REQUEST FOR PRODUCTION NO. 83:**

Please produce exemplars of samples of CYMBALTA that were left with MEDICAL PROFESSIONALS by LILLY pharmaceutical representatives.



**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 83:**

Lilly objects to this Request as overly broad as to time and scope. Lilly also objects to this Request as not limited to documents that would have been viewed by Plaintiff's physician(s).

**REQUEST FOR PRODUCTION NO. 84:**

Please produce all marketing or promotional materials used with MEDICAL PROFESSIONALS by LILLY pharmaceutical representatives, regardless of whether that material was left with the MEDICAL PROFESSIONAL or not.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 84:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request as not limited to documents relating to Cymbalta or discontinuation-emergent adverse events. As part of its production of Form 2253 submissions, Lilly has produced Cymbalta-related marketing and promotional materials, including those shown to medical professionals. Plaintiff has access to these documents.

**REQUEST FOR PRODUCTION NO. 85:**

Please produce DOCUMENTS reflecting LILLY's policies and practices regarding the showing of medical journal articles to MEDICAL PROFESSIONALS by a LILLY pharmaceutical representative.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 85:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which

Plaintiff has access. Lilly also objects to this Request as not limited to documents relating to Cymbalta. Subject to the foregoing objections, Lilly will direct Plaintiff within its prior productions to Lilly's SOPs on pharmaceutical representatives' communication with medical professionals.

**REQUEST FOR PRODUCTION NO. 86:**

Please produce all medical journal articles used by LILLY pharmaceutical representatives to promote CYMBALTA.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 86:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request as not limited to documents relating to discontinuation-emergent adverse events. As part of its production of Form 2253 submissions, Lilly has produced Cymbalta-related marketing and promotional materials, including reprints of journal articles shown to medical professionals. Plaintiff has access to these documents.

**REQUEST FOR PRODUCTION NO. 87:**

Please produce all DOCUMENTS that reflect COMMUNICATIONS between LILLY and the media about CYMBALTA and WITHDRAWAL.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 87:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope. Lilly also objects to this Request to the extent it seeks documents that are publicly available. Moreover, Lilly objects to this Request to the extent it is duplicative of Request No. 71.

**VI. CLIENT-SPECIFIC REQUESTS**

**REQUEST FOR PRODUCTION NO. 88:**

Please produce all DOCUMENTS reflecting any COMMUNICATION between LILLY and the following:

- Dr. Mohammed Bahadori (prescriber) Arthritis Care Center, P.C.  
14904 Jefferson Davis Hwy, Suite 203  
Woodbridge, VA 22192  
(703) 492-6660

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 88:**

Lilly objects to this Request as not limited to documents relating to Cymbalta.

**REQUEST FOR PRODUCTION NO. 89:**

Please produce the custodial file, including but not limited to employment agreements, termination agreements, performance reviews, self-reviews, W-2s, and bonus amounts, for each pharmaceutical representative who called upon the following:

- Dr. Mohammed Bahadori (prescriber) Arthritis Care Center, P.C.  
14904 Jefferson Davis Hwy, Suite 203  
Woodbridge, VA 22192  
(703) 492-6660

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 89:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope. Lilly also objects to this Request as it is not limited to documents relating to Cymbalta or any alleged discontinuation-emergent adverse events potentially arising from Cymbalta treatment and therefore seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence.

**REQUEST FOR PRODUCTION NO. 90:**

Please produce all records, entries, or other data from YOUR pharmaceutical representative database, or any other electronic database used to track sales calls to physicians, regarding each and every sales call made to following:

- Dr. Mohammed Bahadori (prescriber) Arthritis Care Center, P.C.  
14904 Jefferson Davis Hwy, Suite 203  
Woodbridge, VA 22192  
(703) 492-6660

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 90:**

Lilly objects to this Request as not limited to documents relating to Cymbalta.

**REQUEST FOR PRODUCTION NO. 91:**

Please produce all DOCUMENTS reflecting any compensation, gifts, payments, honoraria, or consulting fees given by LILLY to the following:

- Dr. Mohammed Bahadori (prescriber) Arthritis Care Center, P.C.  
14904 Jefferson Davis Hwy, Suite 203  
Woodbridge, VA 22192  
(703) 492-6660

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 91:**

Lilly objects to this Request as not limited to documents relating to Cymbalta.

**REQUEST FOR PRODUCTION NO. 92:**

Please produce any written agreements, contracts, liability releases, or other legal documents that have been drafted and/or executed between LILLY or any third-party representing LILLY and the following:

- Dr. Mohammed Bahadori (prescriber) Arthritis Care Center, P.C.  
14904 Jefferson Davis Hwy, Suite 203

Woodbridge, VA 22192  
(703) 492-6660

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 92:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope. Lilly also objects to this Request as any contract with Dr. Bahadori is irrelevant to the allegations of the Complaint and not likely to lead to the discovery of admissible evidence.

**REQUEST FOR PRODUCTION NO. 93:**

Please produce all DOCUMENTS, including but not limited to marketing materials, brochures, sales aids, “slim jims,” “skiffs,” clinical trials / medical journal articles, PowerPoint presentations, etc., that were given or shown by LILLY pharmaceutical representatives to the following:

- Dr. Mohammed Bahadori (prescriber) Arthritis Care Center, P.C.  
14904 Jefferson Davis Hwy, Suite 203  
Woodbridge, VA 22192  
(703) 492-6660

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 93:**

Lilly objects to this Request as not limited to documents relating to Cymbalta and to the extent records of any documents or marketing materials given or shown by Lilly pharmaceutical representatives to Dr. Bahadori are not contained in Lilly’s sales database.

**REQUEST FOR PRODUCTION NO. 94:**

Please produce all DOCUMENTS reflecting participation in any LILLY-sponsored educational or sales program involving CYMBALTA by the following:

- Dr. Mohammed Bahadori (prescriber) Arthritis Care Center, P.C.  
14904 Jefferson Davis Hwy, Suite 203  
Woodbridge, VA 22192  
(703) 492-6660

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 94:**

Lilly has no objection.

**REQUEST FOR PRODUCTION NO. 95:**

Please produce, for the request above, all materials, including but not limited to PowerPoint presentations, syllabus, medical journal articles, summaries, agendas, etc., provided to or shown as part of the LILLY-sponsored program.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 95:**

Lilly objects to this Request as not limited to documents relating to Cymbalta.

**REQUEST FOR PRODUCTION NO. 96:**

Please produce all records in YOUR possession related to Plaintiff. Please note that this request is in no way limited to medical or psychiatric records, but includes any DOCUMENTS obtained from a third-party by LILLY about the Plaintiff.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 96:**

Lilly objects to this Request to the extent it seeks documents that Lilly has collected or will collect about Plaintiff after the date of the Complaint. As part of investigating the factual allegations of the Complaint, Lilly may collect information about Plaintiff and objects to this Request to the extent it requires Lilly to turn over the fruits of its own investigative efforts. Plaintiff's counsel is better suited to gather information from its own client.

**REQUEST FOR PRODUCTION NO. 97:**

Please produce all DOCUMENTS reflecting any correspondence created in collecting the records described in the above request.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 97:**

Lilly objects to this Request to the extent it seeks documents or communications that would reveal Lilly's legal strategy in this action or are protected by attorney-client privilege, work product doctrine, or any other immunity.

**VII. OTHER REQUESTS**

**REQUEST FOR PRODUCTION NO. 98:**

Please produce all DOCUMENTS identified in YOUR answers to all of Plaintiff's Interrogatories.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 98:**

Lilly objects to this Request as overly broad as Lilly intends to identify categories of documents in answering Plaintiff's interrogatories, including many documents that Lilly has previously produced to which Plaintiff has access.

**REQUEST FOR PRODUCTION NO. 99:**

Please produce all DOCUMENTS from which YOU obtained answers in responding to all of Plaintiff's Interrogatories.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 99:**

Lilly objects to this Request as overly broad as Lilly intends to rely on categories of documents in answering Plaintiff's interrogatories, including many documents that Lilly has previously produced to which Plaintiff has access.

**REQUEST FOR PRODUCTION NO. 100:**

Please produce the custodial file, including but not limited to employment agreements, termination agreements, performance reviews, self-reviews, W-2s, and bonus amounts, for each individual presented by LILLY as a person most knowledgeable under Federal Rule of Civil Procedure 30(b)(6).

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 100:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request as it is not limited to documents relating to Cymbalta or any alleged discontinuation-emergent adverse events potentially arising from Cymbalta treatment and therefore seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence. Lilly has produced documents related to the topics on which its 30(b)(6) witnesses were previously deposed in the *Hexum/Herrera* actions, and Plaintiff has access to those documents. Lilly further objects to this Request as premature as Plaintiff has not yet noticed a deposition of a person most knowledgeable under Federal Rule of Civil Procedure 30(b)(6) in this action.

**REQUEST FOR PRODUCTION NO. 101:**

Please produce all electronic mail (“email”) for the individuals presented by LILLY as a person most knowledgeable under Federal Rule of Civil Procedure 30(b)(6), whether internal or external and whether on LILLY’s current computer operating system, on individual employees’ laptop computers, or archive systems, which contain at least one of the following terms:



**Cy!, dulo!, Aricclaim, Xeristar, Yentreve, Duzela, Dulane, Cymgen, Prozac, Fluox!, Paxil, Parox!, Zoloft, Sertra!, Celexa, Citalop!, Lexapro, Escitalop!, Effexor, venlafa!, Pristiq, desvenlafax!, milnacipr!, levomilnacipr!, SSRI!, SNRI!, or anti!,**

*and* at least one of the following terms:

**DEAE!, discon!, withd!, taper!, cold w/1turkey, addict!, habit!, paresth!, zap!, electric w/4 shock, dizz!, Rosenbaum, Schatzberg, Glenmullen, half-life, “missed dose,” downregu!, “greater than or equal to,” Perahia, enteric, or time-release.**

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 101:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request as it is not limited to documents relating to Cymbalta or any alleged discontinuation-emergent adverse events potentially arising from Cymbalta treatment and therefore seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence. Lilly has produced documents related to the topics on which its 30(b)(6) witnesses were previously deposed in the *Hexum/Herrera* actions, and Plaintiff has access to those documents. Lilly further objects to search terms such as “anti!”, “addict!”, “habit!”, “greater than or equal to”, or “delayed release” as overly broad and far beyond the scope of the allegations of the Complaint. Lilly further objects to this Request as premature as Plaintiff has not yet noticed a deposition of a person most knowledgeable under Federal Rule of Civil Procedure 30(b)(6) in this case.

**REQUEST FOR PRODUCTION NO. 102:**

Please produce all DOCUMENTS in LILLY's possession, custody or control concerning any governmental investigations of LILLY in relation to CYMBALTA and, in any way, with WITHDRAWAL.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 102:**

Lilly is not aware of any governmental investigations of Lilly in relation to Cymbalta and discontinuation symptoms.

**REQUEST FOR PRODUCTION NO. 103:**

With respect to Lilly's Patient Assistance and/or Lilly Cares Program for CYMBALTA, please produce all documents regarding Lilly's decision to establish the program; its structure and budget; its criteria for deciding which patients qualify for the program; and any complaints, questions, or comments received from participants, physicians, or pharmacies.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 103:**

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope. The Complaint contains no allegations that Plaintiff participated in Lilly's Patient Assistance or Lilly Cares Program, and therefore this Request seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence.

**REQUEST FOR PRODUCTION NO. 104:**

Please produce all DOCUMENTS pertaining to Lilly's provision of CYMBALTA to Plaintiff, if applicable, as part of Lilly's Patient Assistance and/or Lilly Cares program.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 104:**

Lilly has no objection.

**REQUEST FOR PRODUCTION NO. 105:**

Please produce all Corporate Integrity Agreements LILLY has entered into with any government for any reason.

**OBJECTIONS TO REQUEST FOR PRODUCTION NO. 105:**

Lilly objects to this Request as overly broad as it is not limited to documents related to Cymbalta and therefore seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence. Lilly further objects to this Request to the extent it seeks publicly available information. (*See* <http://www.lilly.com/Documents/CIA.pdf>)

Respectfully Submitted,

Dated: February 23, 2015

By: \_\_\_\_\_/s/  
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**CERTIFICATE OF SERVICE**

I, Jeffrey T. Bozman, hereby certify that on the 23rd day of February, 2015, I have served Plaintiff's counsel in this action with a copy of Defendant's Objections to Plaintiff's First Set of Requests for Production by mailing a copy of the same by United States Mail, postage prepaid, and electronic mail to the following address:

Peter A. Miller  
**Miller Legal LLC**  
175 S. Pantops Drive, Third Floor  
Charlottesville, VA 2291  
Telephone (434) 529-6909  
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PMiller@MillerLegalLLC.com  
*Counsel for Gilda Hagan-Brown*

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*Counsel for Eli Lilly and Company*

## Exhibit 4-C

**UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF VIRGINIA  
ALEXANDRIA DIVISION**

GILDA HAGAN-BROWN

Plaintiff,

v.

ELI LILLY AND COMPANY, an Indiana  
corporation,

Defendant.

CASE NO.: 1:14-CV-01614

**DEFENDANT’S RESPONSES TO PLAINTIFF’S FIRST SET OF REQUESTS FOR  
PRODUCTION OF DOCUMENTS**

Defendant Eli Lilly and Company (“Defendant” or “Lilly”) hereby submits its responses to Plaintiff’s First Set of Requests for Production, as follows:

**GENERAL STATEMENT**

The following responses are subject to Lilly’s Objections to Plaintiff’s First Set of Requests for Production served on February 23, 2015 pursuant to Federal Rule of Civil Procedure 34 and Local Civil Rule 26 and, for the sake of brevity, not repeated herein. Lilly has not fully completed its investigation of the facts relating to this case, its discovery, or its preparation for trial. Both discovery and independent investigation are ongoing. Therefore, all responses contained herein are based solely upon such information and documents as are both presently available and specifically known to Lilly. Lilly reserves the right to supplement these responses as discovery and this investigation proceed. Lilly’s responses are in accordance with the requirements of the Federal Rules of Civil Procedure, the Local Rules, and any applicable Court Orders.

**SPECIFIC RESPONSES TO REQUESTS FOR PRODUCTION**

**I. FDA DOCUMENTS**

**REQUEST FOR PRODUCTION NO. 1:**

Please produce the Electronic Common Technical Document (eCTD) or equivalent electronic submission for all CYMBALTA indications, whether that indication was approved or denied, including but not limited to: Major Depressive Disorder (MDD), Generalized Anxiety Disorder (GAD), Neuropathic Pain from Diabetes, Chronic Pain, Chronic Musculoskeletal Pain, Fibromyalgia, MDD Maintenance, GAD Maintenance, and Stress Urinary Incontinence (SUI).

**RESPONSE TO REQUEST FOR PRODUCTION NO. 1:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly responds that its Investigational New Drug ("IND") submission and New Drug Application ("NDA") submissions to FDA for Cymbalta indications can be found in Lilly's existing production at CYM-00000001 - CYM-01725262; CYM-01737200 - CYM-01737203; CYM-01737265 - CYM-01757110; and CYM-01757111 - CYM-01758619.

**REQUEST FOR PRODUCTION NO. 2:**

Please produce the Summary Basis of Approval for CYMBALTA for the following indications: Major Depressive Disorder (MDD), Generalized Anxiety Disorder (GAD), Neuropathic Pain from Diabetes, Chronic Pain, Chronic Musculoskeletal Pain, Fibromyalgia, MDD Maintenance, and GAD Maintenance.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 2:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 3:**

Please produce all Periodic Safety Updates regarding CYMBALTA for the following indications: Major Depressive Disorder (MDD), Generalized Anxiety Disorder (GAD), Neuropathic Pain from Diabetes, Chronic Pain, Chronic Musculoskeletal Pain, Fibromyalgia, MDD Maintenance, and GAD Maintenance.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 3:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly responds that its Periodic Safety Update Reports can be found in its existing production at CYM-00715114 - CYM-00717615; CYM-00719282 - CYM-01102877; CYM-00861952 - CYM-00862115; CYM-00857864 - CYM-00860751; CYM-00947704- CYM-00951649; CYM-00963610 - CYM-009674548; CYM-01103692 - CYM-001106656; CYM-01099044 - CYM-01102877; CYM-01117943 - CYM-01122174; CYM-00131805 - CYM-00140607; CYM-00289558 - CYM-00299778; CYM-00331576 - CYM-00342389; and CYM-00512955 - CYM-00525732.

**REQUEST FOR PRODUCTION NO. 4:**

Please produce all Annual Safety Updates regarding CYMBALTA for the following indications: Major Depressive Disorder (MDD), Generalized Anxiety Disorder (GAD), Neuropathic Pain from Diabetes, Chronic Pain, Chronic Musculoskeletal Pain, Fibromyalgia, MDD Maintenance, and GAD Maintenance.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 4:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly refers Plaintiff to its response to Request No. 3



**REQUEST FOR PRODUCTION NO. 5:**

Please produce the electronic Investigational New Drug (“IND”) file for CYMBALTA.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 5:**

Subject to and without waiving its Objections to Plaintiff’s First Set of Requests for Production, Lilly refers Plaintiff to its response to Request No. 1.

**REQUEST FOR PRODUCTION NO. 6:**

Please produce all warning letters sent to YOU from the FDA regarding CYMBALTA.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 6:**

Subject to and without waiving its Objections to Plaintiff’s First Set of Requests for Production, Lilly responds that letters it received from FDA’s Division of Drug Marketing, Advertising, and Communications (“DDMAC”) regarding Cymbalta can be found in its existing production at CYM-01236531 - CYM-01236535; CYM-1250524 - CYM-01250531; and CYM-01735325 - CYM-01735329; CYM-01735321 - CYM-01735324. Additional letters are publicly available at

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/default.htm>

**REQUEST FOR PRODUCTION NO. 7:**

Please produce YOUR responses to all warning letters sent to YOU from the FDA regarding CYMBALTA.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 7:**

Subject to and without waiving its Objections to Plaintiff’s First Set of Requests for Production, Lilly responds that its responses to letters it received from FDA’s DDMAC

regarding Cymbalta can be found in its existing production at CYM-01737172; CYM-01258099 - CYM-01258103; CYM-01258154 - CYM-01258160; and CYM-01737181 - CYM-01737199; CYM-01737173 - CYM-01737177; CYM-01735315 - CYM-01735320; and CYM-01735309 - CYM-01735314.

**REQUEST FOR PRODUCTION NO. 8:**

Please produce the transcript of any FDA Advisory Committee meetings regarding CYMBALTA for any indication.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 8:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 9:**

Please produce any DOCUMENTS submitted to the FDA as part of any Advisory Committee meeting related to CYMBALTA.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 9:**

Lilly refers Plaintiff to its objections this Request.

**REQUEST FOR PRODUCTION NO. 10:**

Please produce any and all Form 483 and/or Warning Letters that YOU received from the FDA related to CYMBALTA.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 10:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly refers Plaintiff to its response to Request No. 6.

**REQUEST FOR PRODUCTION NO. 11:**

Please produce YOUR responses to all Form 483 and/or Warning Letters that YOU received from the FDA related to CYMBALTA.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 11:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly refers Plaintiff to its response to Request No. 7.

**REQUEST FOR PRODUCTION NO. 12:**

Please produce all DOCUMENTS reflecting any settlements, agreements, resolutions, fines, sanctions and/or additional regulatory actions that arose as a result of the Form 483 and/or Warning Letters that YOU received from the FDA related to CYMBALTA.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 12:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly refers Plaintiff to its responses to Requests Nos. 6 and 7. Beyond the resolutions described therein, there were no additional regulatory actions that arose as a result of letters Lilly received from DDMAC related to Cymbalta.

**REQUEST FOR PRODUCTION NO. 13:**

Please produce all DOCUMENTS related to any COMMUNICATIONS with the FDA about CYMBALTA containing any of the following terms (or any derivative term): DEAE, withdrawal, discontinuation or discontinuing, dependence, habit-forming, addiction, quitting, tapering, brain zaps, electric shock, down regulation, half-life, missed dose, "greater than or equal to," Perahia, Rosenbaum, or Schatzberg.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 13:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 14:**

Please produce all DOCUMENTS related to any COMMUNICATIONS with the FDA about Prozac or fluoxetine containing any of the following terms (or any derivative term): DEAE, withdrawal, discontinuation or discontinuing, dependence, habit-forming, addiction, quitting, tapering, brain zaps, electric shock, down regulation, half-life, missed dose, “greater than or equal to,” Perahia, Rosenbaum, or Schatzberg.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 14:**

Subject to and without waiving its Objections to Plaintiff’s First Set of Requests for Production, Lilly responds that documents relating to Prozac can be found in its existing production at CYMPRO-0000000001 - CYMPRO-0000053299.

**REQUEST FOR PRODUCTION NO. 15:**

Please produce all DOCUMENTS related to any COMMUNICATIONS with the FDA about Zyprexa or olanzapine containing any of the following terms (or any derivative term): DEAE, withdrawal, discontinuation or discontinuing, dependence, habit-forming, addiction, quitting, tapering, brain zaps, electric shock, down regulation, half-life, missed dose, “greater than or equal to,” Perahia, Rosenbaum, or Schatzberg.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 15:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 16:**

Please produce all DOCUMENTS reflecting COMMUNICATIONS with the FDA about the section of the US LABEL titled “Discontinuation of Treatment with Cymbalta.”

**RESPONSE TO REQUEST FOR PRODUCTION NO. 16:**

Subject to and without waiving its Objections to Plaintiff’s First Set of Requests for Production, Lilly refers Plaintiff to its response to Request No. 1.

**REQUEST FOR PRODUCTION NO. 17:**

Please produce all DOCUMENTS reflecting COMMUNICATIONS with the FDA about the sections of the US LABEL titled “Dosage and Administration” or “Medication Administration” or “Information for Patients” (depending on year).

**RESPONSE TO REQUEST FOR PRODUCTION NO. 17:**

Subject to and without waiving its Objections to Plaintiff’s First Set of Requests for Production, Lilly refers Plaintiff to its responses to Requests Nos. 1 and 16.

**REQUEST FOR PRODUCTION NO. 18:**

Please produce all DOCUMENTS that reflect COMMUNICATIONS between LILLY and the FDA concerning LILLY’s Medical Information Letters, or similar letters, concerning the potential risk of withdrawal or discontinuation from CYMBALTA.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 18:**

Subject to and without waiving its Objections to Plaintiff’s First Set of Requests for Production, Lilly responds that medical information letters concerning Cymbalta and discontinuation-emergent adverse events can be found in its existing production at CYM-01727818 - CYM-01727884 and CYM-01766604 - CYM-01766611.

**REQUEST FOR PRODUCTION NO. 19:**

Please produce all COMMUNICATIONS between YOU and the FDA concerning the half-life of CYMBALTA.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 19:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly refers Plaintiff to its responses to Requests Nos. 1, 16, and 17.

**REQUEST FOR PRODUCTION NO. 20:**

Please produce all COMMUNICATIONS between YOU and the FDA concerning the enteric coating of CYMBALTA.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 20:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly refers Plaintiff to its responses to Requests Nos. 1, 16, 17, and 19.

**REQUEST FOR PRODUCTION NO. 21:**

Please produce a copy of each FDA-approved version of the package insert for CYMBALTA used by LILLY since it began marketing CYMBALTA in the United States.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 21:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly responds Lilly refers Plaintiff to Attachment E, which identifies the Bates numbers corresponding to each FDA-approved version of the Cymbalta package insert that could be located through a reasonably diligent search. Additional FDA-approved versions of the Cymbalta package insert are publicly available here:

<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Overview&>

DrugName=CYMBALTA&CFID=7507737&CFTOKEN=e8433ca4c6d9e77f-EE76B6D9-D59C-F73B-4B4ACFD7754D8B36

**REQUEST FOR PRODUCTION NO. 22:**

Please produce a copy of each version of the LABEL for CYMBALTA in each foreign country wherein CYMBALTA was approved for marketing in that country.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 22:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly responds that it will produce responsive documents that can be identified through a reasonably diligent search of its BLUE and REGULUS databases, which include approved labeling for Cymbalta submitted to the repositories by Lilly's global affiliates since November 2008.

**REQUEST FOR PRODUCTION NO. 23:**

Please produce the electronic Adverse Event Reporting database for CYMBALTA.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 23:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly refers Plaintiff to Attachment B, which provides the Bates numbers corresponding to reports made to FDA of adverse events potentially linked to Cymbalta, including so-called "MedWatch" forms. Lilly further refers Plaintiff to CYM-02055041-CYM-02055073, which constitutes Cymbalta postmarketing adverse event data from the Lilly Safety System for serious, unlisted events coded with at least one of the terms "drug withdrawal convulsions," "drug withdrawal headache," "drug withdrawal syndrome," "withdrawal hypertension," or "withdrawal syndrome."

**II. INTERNAL COMMUNICATIONS ABOUT CYMBALTA**

**REQUEST FOR PRODUCTION NO. 24:**

Please produce all DOCUMENTS reflecting LILLY's internal COMMUNICATIONS and/or deliberations concerning the section of the US CYMBALTA LABEL titled "Discontinuation of Treatment with Cymbalta," including not limited to all emails, memorandums, drafts, comments, edits, redlines, or discussions about those edits of those sections of the US CYMBALTA LABEL.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 24:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 25:**

Please produce all DOCUMENTS reflecting LILLY's internal COMMUNICATIONS and/or deliberations concerning the section of the US CYMBALTA LABEL titled "Dosage and Administration" or "Medication Administration" or "Information for Patients" (depending on year), including not limited to all emails, memorandums, drafts, comments, edits, redlines, or discussions about those edits of the that section of the US CYMBALTA LABEL.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 25:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 26:**

Please produce all DOCUMENTS reflecting LILLY's internal COMMUNICATIONS and/or deliberations concerning the following sentences in the US CYMBALTA LABEL as it was approved in 2004, including but not limited to all emails, memorandums, drafts, comments, edits, redlines, or discussions about those edits: "Duloxetine should be swallowed whole and



should not be chewed or crushed, nor should the contents be sprinkled on food or mixed with liquids. All of these might affect the enteric coating.”

**RESPONSE TO REQUEST FOR PRODUCTION NO. 26:**

Lilly refers Plaintiff to its objections this Request.

**REQUEST FOR PRODUCTION NO. 27:**

Please produce all DOCUMENTS that reflect LILLY’s reason for changing the US LABEL concerning “Discontinuation of Treatment with Cymbalta” in 2008 from “the following symptoms occurred at a rate greater than or equal to 2%” to “the following symptoms occurred at a rate greater than or equal to 1%.”

**RESPONSE TO REQUEST FOR PRODUCTION NO. 27:**

Subject to and without waiving its Objections to Plaintiff’s First Set of Requests for Production, Lilly refers Plaintiff to its response to Interrogatory No. 14.

**REQUEST FOR PRODUCTION NO. 28:**

Please produce all DOCUMENTS that reflect LILLY’s reason for adding to the 2009 US CYMBALTA LABEL “or tapered” in the context of “Following abrupt ... discontinuation ...” in the section titled “Discontinuation of Treatment with Cymbalta.”

**RESPONSE TO REQUEST FOR PRODUCTION NO. 28:**

Subject to and without waiving its Objections to Plaintiff’s First Set of Requests for Production, Lilly refers Plaintiff to its response to Interrogatory No. 15.

**REQUEST FOR PRODUCTION NO. 29:**

Please produce all DOCUMENTS that reflect LILLY's reason for changing the US CYMBALTA LABEL in 2012 from "the following symptoms occurred at a rate greater than or equal to 1%" to "at 1% or greater" in the section titled "Discontinuation of Treatment with Cymbalta."

**RESPONSE TO REQUEST FOR PRODUCTION NO. 29:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 30:**

Please produce all DOCUMENTS that reflect LILLY's reason for creating CYMBALTA as capsules containing enteric-coated pellets of duloxetine hydrochloride.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 30:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 31:**

Please produce all DOCUMENTS reflecting LILLY's internal COMMUNICATIONS and/or deliberations concerning the design of CYMBALTA as enteric-coated pellets contained within a capsule.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 31:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 32:**

Please produce all DOCUMENTS reflecting LILLY's internal COMMUNICATIONS and/or deliberations concerning the development of a dosage of CYMBALTA below 20mg.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 32:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 33:**

Please produce all DOCUMENTS reflecting LILLY's internal COMMUNICATIONS and/or deliberations concerning the development of CYMBALTA as a scored tablet.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 33:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 34:**

Please produce all memoranda, presentations, and/or reports, whether prepared internally or provided to LILLY by a third-party, that discuss, in any way, CYMBALTA and WITHDRAWAL.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 34:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly responds that it has already produced a significant amount of documents responsive to this request and such documents can be found in Lilly's existing production, and Lilly refers Plaintiff to the following documents as examples: CYM-01928754 - CYM-01928834; CYM-01952646 - CYM-01952676; CYM-02156153 - CYM-02156171; CYM-01952953 - CYM-01962959; CYM-01782498 - CYM-01782503

**REQUEST FOR PRODUCTION NO. 35:**

Please produce all electronic mail ("email") for the individuals identified in Interrogatory Nos. 1 & 3, whether internal or external and whether on LILLY's current computer operating

system, on individual employees' laptop computers, or archive systems, which contain at least one of the following terms:

**Cy!, dulo!, Ariclain, Xeristar, Yentreve, Duzela, Dulane, Cymgen, Prozac, Fluox!, Paxil, Parox!, Zoloft, Sertra!, Celexa, Citalop!, Lexapro, Escitalop!, Effexor, venlafa!, Pristiq, desvenlafax!, milnacipr!, levomilnacipr!, SSRI!, SNRI!, or anti!,**

*and* at least one of the following terms:

**DEAE!, discon!, withd!, taper!, cold w/1turkey, addict!, habit!, paresth!, zap!, electric w/4 shock, dizz!, Rosenbaum, Schatzberg, Glenmullen, half-life, "missed dose," downregu!, "greater than or equal to," Perahia, enteric, pellets, "delayed release."**

**RESPONSE TO REQUEST FOR PRODUCTION NO. 35:**

Lilly refers Plaintiff to its objections to this Request and its objections to Interrogatories Nos. 1 and 3.

**REQUEST FOR PRODUCTION NO. 36:**

Please produce all DOCUMENTS that reflect LILLY's internal COMMUNICATIONS and/or deliberations concerning any and all letters used by LILLY to respond to inquiries regarding CYMBALTA and DEAEs, discontinuation, withdrawal, dependence, or addiction.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 36:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 37:**

Please produce all DOCUMENTS that reflect LILLY's internal COMMUNICATIONS and/or deliberations concerning any of LILLY's Medical Information Letters, or similar letters, concerning the potential risk of withdrawal or discontinuation from CYMBALTA.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 37:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly refers Plaintiff to its response to Request No. 18.

**REQUEST FOR PRODUCTION NO. 38:**

Please produce all minutes of meetings of any LILLY committee, working group, department, board, etc. where CYMBALTA and WITHDRAWAL were discussed.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 38:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 39:**

Please produce all DOCUMENTS that reflect LILLY's internal COMMUNICATIONS and/or deliberations concerning why the rate of WITHDRAWAL reflected in the PERAHIA article was not included in the US LABEL.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 39:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 40:**

Please produce all DOCUMENTS that reflect LILLY's internal COMMUNICATIONS and/or deliberations concerning why the rate of WITHDRAWAL reflected in the PERAHIA article was included in the European LABEL.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 40:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly refers Plaintiff to CYM-01865850 - CYM-01865854 and its response to Interrogatory No. 17.

**REQUEST FOR PRODUCTION NO. 41:**

Please produce all DOCUMENTS that reflect LILLY's internal COMMUNICATIONS concerning discontinuation or withdrawal symptoms upon discontinuation of Effexor, including but not limited to any discussion concerning the language contained in the US Effexor LABEL concerning WITHDRAWAL.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 41:**

Lilly refers Plaintiff to its objections to this Request.

**III. COMMUNICATIONS WITH MEDICAL PROFESSIONALS**

**REQUEST FOR PRODUCTION NO. 42:**

Please produce any "Dear Healthcare Professional" or similar letters to doctors, pharmacies or other groups, organizations about CYMBALTA.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 42:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly responds that its Dear Healthcare Professional letter concerning Cymbalta can be found in its existing production at CYM-01737200 - CYM-01737201.

**REQUEST FOR PRODUCTION NO. 43:**

Please produce all DOCUMENTS that contain a record or description of COMMUNICATIONS to LILLY from MEDICAL PROFESSIONALS or the public, including but not limited to call logs, inquiring about CYMBALTA that mention DEAEs, withdrawal, discontinuation or discontinuing, dependence, habit-forming, addiction, quitting, tapering, brain zaps, electric shock, down regulation, half-life (or any related or derivative terms).

**RESPONSE TO REQUEST FOR PRODUCTION NO. 43:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly responds that documents reflecting communications from health care professionals and consumers can be found in Lilly's existing production at CYM-02777356 - CYM-02777616.

**REQUEST FOR PRODUCTION NO. 44:**

Please produce any and all letters used by LILLY to respond to inquiries regarding CYMBALTA and DEAEs, discontinuation, withdrawal, dependence, or addiction.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 44:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly refers Plaintiff to its response to Request No. 18.

**REQUEST FOR PRODUCTION NO. 45:**

Please produce a copy of each and every version of LILLY's "Medical Information Letter" or similar letters to doctors, pharmacies or other groups, organizations or entities discussing the potential risk of withdrawal or discontinuation from CYMBALTA.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 45:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly refers Plaintiff to its responses to Requests Nos. 18 and 44.

**REQUEST FOR PRODUCTION NO. 46:**

Please produce all DOCUMENTS that identify MEDICAL PROFESSIONALS to whom LILLY sent a Medical Information Letter concerning the potential risk of withdrawal or discontinuation from CYMBALTA (e.g., an Excel spreadsheet or Access spreadsheet).

**RESPONSE TO REQUEST FOR PRODUCTION NO. 46:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 47:**

Please produce any and all DOCUMENTS that reflect each inquiry from a MEDICAL PROFESSIONAL concerning Cymbalta and withdrawal or discontinuation, including but not limited to written letters, telephone calls, online requests, sales representative relay.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 47:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly refers Plaintiff to its response to Request No. 43.

**IV. MEDICAL LITERATURE AND CONTINUING MEDICAL EDUCATION**

**REQUEST FOR PRODUCTION NO. 48:**

Please produce all publication plans for CYMBALTA, whether prepared internally or by a third-party.



**RESPONSE TO REQUEST FOR PRODUCTION NO. 48:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly responds that it will produce publication plans for Cymbalta that can be located through a reasonably diligent search.

**REQUEST FOR PRODUCTION NO. 49:**

Please produce all DOCUMENTS reflecting LILLY's involvement in the drafting, editing, and publication the PERAHIA ARTICLE, including but not limited to all email communications, article drafts, and publication plans relating to the PERAHIA ARTICLE.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 49:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 50:**

Please produce the study protocol and final study reports for each of the CYMBALTA trials discussed in the PERAHIA ARTICLE.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 50:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly responds that the study protocols and final study reports for each of the Cymbalta trials discussed in the PERAHIA ARTICLE can be found in Lilly's existing production at CYM-01020818 - CYM-01033963; CYM-01054242 - CYM-01057304; CYM-01033964 - CYM-01035948; CYM-01028897 - CYM-01030817; CYM-01057305 - CYM-01059489; CYM-01026706 - CYM-01028896; CYM-01059490 - CYM-01078316; CYM-00870792 - CYM-00876204; that CYM-01493802 - CYM-01531668.

**REQUEST FOR PRODUCTION NO. 51:**

Please produce the raw data, including but not limited to the case report forms for each of the CYMBALTA trials discussed in the PERAHIA ARTICLE.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 51:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 52:**

Please produce all DOCUMENTS reflecting the amount of compensation given to the authors of the PERAHIA ARTICLE, including but not limited to non-listed authors in the final publication.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 52:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 53:**

Please produce a copy of the articles identified in Interrogatories Nos. 18 & 19.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 53:**

Lilly refers Plaintiff to its objections to this Request and its objections to Interrogatories Nos. 18 and 19.

**REQUEST FOR PRODUCTION NO. 54:**

Please produce all DOCUMENTS reflecting LILLY's involvement in the drafting, editing, and publication of those articles identified in Interrogatories Nos. 18 & 19.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 54:**

Lilly refers Plaintiff to its objections to this Request and its objections to Interrogatories Nos. 18 and 19.

**REQUEST FOR PRODUCTION NO. 55:**

Please produce all DOCUMENTS reflecting the amount of compensation given to the authors of those articles identified in Interrogatories Nos. 18 &19, including but not limited to compensation associated with the article's publication. In lieu of producing these documents, Plaintiff would accept an Excel chart listing each author and the total amount of compensation received by that author by LILLY, by year.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 55:**

Lilly refers Plaintiff to its objections to this Request and its objections to Interrogatories Nos. 18 and 19.

**REQUEST FOR PRODUCTION NO. 56:**

Please produce all DOCUMENTS reflecting any communications between LILLY and the authors of the articles identified in Interrogatories Nos. 18 &19 concerning discontinuation or withdrawal symptoms upon discontinuation of any SSRI or SNRI, including but not limited to CYMBALTA, Effexor, Prozac, Paxil and Zoloft.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 56:**

Lilly refers Plaintiff to its objections to this Request and its objections to Interrogatories Nos. 18 and 19.

**REQUEST FOR PRODUCTION NO. 57:**

Please produce all DOCUMENTS reflecting any COMMUNICATIONS between LILLY and Mario Fava concerning discontinuation or withdrawal symptoms upon discontinuation of any SSRI or SNRI, including but not limited to CYMBALTA, Effexor, Prozac, Paxil and Zoloft.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 57:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly refers Plaintiff to Dr. Fava's third-party production: FAVA-001 - FAVA-144.

**REQUEST FOR PRODUCTION NO. 58:**

Please produce all DOCUMENTS reflecting any COMMUNICATIONS between LILLY and Jerrold Rosenbaum concerning discontinuation or withdrawal symptoms upon discontinuation of any SSRI or SNRI, including but not limited to CYMBALTA, Effexor, Prozac, Paxil and Zoloft.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 58:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly refers Plaintiff to Dr. Rosenbaum's third-party production: ROSENBAUM-0001 - ROSENBAUM-0014.

**REQUEST FOR PRODUCTION NO. 59:**

Please produce all DOCUMENTS reflecting any COMMUNICATIONS between LILLY and Peter Haddad concerning discontinuation or withdrawal symptoms upon discontinuation of any SSRI or SNRI, including but not limited to CYMBALTA, Effexor, Prozac, Paxil and Zoloft.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 59:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 60:**

Please produce all DOCUMENTS reflecting any communications between LILLY and Alan Schatzberg concerning discontinuation or withdrawal symptoms upon discontinuation of any SSRI or SNRI, including but not limited to CYMBALTA, Effexor, Prozac, Paxil and Zoloft.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 60:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 61:**

Please produce all CYMBALTA clinical trials wherein DEAEs or withdrawal symptoms were measured, noted, calculated, or where data concerning DEAEs or withdrawal was obtained, regardless of whether measuring DEAEs or withdrawal symptoms was part of the trial's original protocol. Please note this request is not limited in time (i.e., pre-approval or post-approval), geography (i.e., location of the study or clinical trial), type (i.e., placebo-controlled, active-controlled, or open), authorship (i.e., LILLY-sponsored or conducted by a third-party), or whether the trial was FDA-sanctioned. This request seeks all DEAE or withdrawal clinical data within LILLY's possession.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 61:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly refers Plaintiff to Attachment A, which identifies the Bates numbers corresponding to Cymbalta clinical trials located through a reasonably diligent search of Lilly's existing production. They are organized generally according to the NDA to which they relate and include, among others, clinical trials that measured discontinuation-emergent adverse events.

**REQUEST FOR PRODUCTION NO. 62:**

Please produce any presentations, PowerPoint presentations, memoranda, product brochures / marketing materials, and/or audio/video recordings, used by LILLY with regard to CYMBALTA that mention the potential risk of withdrawal or discontinuation from CYMBALTA.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 62:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly refers Plaintiff to its responses to Requests Nos. 34 and 67. Lilly further responds that responsive materials can be found in Lilly's existing production and refers Plaintiff to the following documents as examples: CYM-01754727 - CYM-01754761; CYM-01726950 - CYM-01726961; CYM-01726905 - CYM-01726916; and CYM-01743625 - CYM-01743650.

**REQUEST FOR PRODUCTION NO. 63:**

Please produce all Continuing Medical Education ("CME") presentations or programs, including those DOCUMENTS given to attendees of CMEs, sponsored or created by YOU that mention DEAEs, withdrawal, discontinuation, dependence or addiction, whether related to CYMBALTA or not, including but not limited to presentations that reference Prozac / fluoxetine and/or Effexor / venlafaxine.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 63:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly responds that materials from Lilly-sponsored Continuing Medical Education presentations or programs related to Cymbalta or Prozac can be found in Lilly's existing production and refers Plaintiff to the follow documents as examples: CYMPRO-0000053089 -

CYMPRO-0000053118; CYMPRO-0000053220 - CYMPRO-0000053253; CYMPRO-0000053254 - CYMPRO-0000053297; and CYM-02051103 - CYM-02051117.

**REQUEST FOR PRODUCTION NO. 64:**

Please produce DOCUMENTS which list, in whatever interval those lists were compiled, key opinion leaders / thought leaders related to CYMBALTA.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 64:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly responds that information about non-employee doctors associated with Lilly in relation to Cymbalta can be found in Faculty Reports, Contract Status Reports, and Activity Detail Reports that can be found within its existing production at CYM-02739356 - CYM-02777355.

**REQUEST FOR PRODUCTION NO. 65:**

Please produce all DOCUMENTS reflecting any agreement with a key opinion leader / thought leader related to CYMBALTA.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 65:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 66:**

Please produce all DOCUMENTS reflecting any compensation given to a key opinion leader / thought leader related to CYMBALTA.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 66:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly refers Plaintiff to its response to Request No. 64.

**V. SALES AND MARKETING**

**REQUEST FOR PRODUCTION NO. 67:**

Please produce all television commercials for CYMBALTA.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 67:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly refers Plaintiff to Attachment C, which identifies the Bates numbers corresponding to examples of Cymbalta advertisements, promotional materials, and related documents.

**REQUEST FOR PRODUCTION NO. 68:**

Please produce all radio commercials for CYMBALTA.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 68:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly refers Plaintiff to its response to Request No. 67.

**REQUEST FOR PRODUCTION NO. 69:**

Please produce all advertisements in magazines for CYMBALTA.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 69:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly refers Plaintiff to its response to Request No. 67.



**REQUEST FOR PRODUCTION NO. 70:**

Please produce all advertisements on the internet for CYMBALTA.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 70:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly refers Plaintiff to its response to Request No. 67.

**REQUEST FOR PRODUCTION NO. 71:**

Please produce all press releases ever issued by LILLY with regard to CYMBALTA.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 71:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly responds that Lilly press releases are publicly available at <http://lilly.mediaroom.com/>

**REQUEST FOR PRODUCTION NO. 72:**

Please produce all COMMUNICATIONS with WebMD regarding CYMBALTA.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 72:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 73:**

Please produce every marketing plan, including all drafts, for CYMBALTA, regardless of whether that plan was prepared internally or by a third-party.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 73:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly responds that brand plans for Cymbalta can be found in Lilly's existing

production and refers to the following documents as examples: CYM-01725585 - CYM-01725610; CYM-01725697 - CYM-01725756; CYM-01726046 - CYM-01726052; CYM-02302344 - CYM-02302350.

**REQUEST FOR PRODUCTION NO. 74:**

Please produce any report or DOCUMENT reflecting the effectiveness of LILLY's marketing campaigns for CYMBALTA.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 74:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 75:**

Please produce every business plan, including all drafts, for CYMBALTA, regardless of whether that plan was prepared internally or by a third-party.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 75:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly refers Plaintiff to its response to Request No. 73.

**REQUEST FOR PRODUCTION NO. 76:**

Please produce every launch plan, including all drafts, for CYMBALTA, regardless of whether that plan was prepared internally or by a third-party.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 76:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 77:**

Please produce all COMMUNICATIONS between LILLY and any third-party marketing company or consultant concerning CYMBALTA's direct-to-consumer marketing that discusses, in any way, WITHDRAWAL.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 77:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 78:**

Please produce all COMMUNICATIONS between LILLY and any third-party marketing company or consultant concerning CYMBALTA's direct-to-consumer marketing that discusses, in any way, once-a-day versus twice-a-day dosing.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 78:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 79:**

Please produce all DOCUMENTS reflecting any contract or agreement between LILLY and a third-party company or consultant related to CYMBALTA's direct-to-consumer marketing.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 79:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 80:**

Please produce all market surveys and focus group results / summaries for CYMBALTA.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 80:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly responds that it will produce market surveys and related materials concerning Cymbalta and discontinuation-emergent adverse events, if any, that can be located through a reasonably diligent search.

**REQUEST FOR PRODUCTION NO. 81:**

Please produce all versions of materials and DOCUMENTS, including but not limited to videos or audio recordings, used to train LILLY pharmaceutical representatives about CYMBALTA.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 81:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly refers Plaintiff to Attachment D, which identifies the Bates numbers corresponding to Lilly's standard operating procedures ("SOPs"). Lilly further refers Plaintiff to training materials for sales representatives relating to Cymbalta, which can be found in its existing production at CYM-01728139- CYM-01732494.

**REQUEST FOR PRODUCTION NO. 82:**

Please produce DOCUMENTS reflecting LILLY's policies and practices regarding communicating with a MEDICAL PROFESSIONAL by a LILLY pharmaceutical representative.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 82:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly refers Plaintiff to its response to Request No. 81.

**REQUEST FOR PRODUCTION NO. 83:**

Please produce exemplars of samples of CYMBALTA that were left with MEDICAL PROFESSIONALS by LILLY pharmaceutical representatives.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 83:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly responds that it will produce exemplars of the packaging and accompanying materials for samples of Cymbalta.

**REQUEST FOR PRODUCTION NO. 84:**

Please produce all marketing or promotional materials used with MEDICAL PROFESSIONALS by LILLY pharmaceutical representatives, regardless of whether that material was left with the MEDICAL PROFESSIONAL or not.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 84:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly refers Plaintiff to its response to Request No. 67.

**REQUEST FOR PRODUCTION NO. 85:**

Please produce DOCUMENTS reflecting LILLY's policies and practices regarding the showing of medical journal articles to MEDICAL PROFESSIONALS by a LILLY pharmaceutical representative.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 85:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly refers Plaintiff to its response to Request No. 81.

**REQUEST FOR PRODUCTION NO. 86:**

Please produce all medical journal articles used by LILLY pharmaceutical representatives to promote CYMBALTA.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 86:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly refers Plaintiff to its response to Request No. 81, which includes reprints of journal articles for use with medical professionals, for example CYM-01092327 - CYM-01092345 and CYM-01092356 - CYM-1092367.

**REQUEST FOR PRODUCTION NO. 87:**

Please produce all DOCUMENTS that reflect COMMUNICATIONS between LILLY and the media about CYMBALTA and WITHDRAWAL.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 87:**

Lilly refers Plaintiff to its objections to this Request.

**VI. CLIENT-SPECIFIC REQUESTS**

**REQUEST FOR PRODUCTION NO. 88:**

Please produce all DOCUMENTS reflecting any COMMUNICATION between LILLY and the following:

- Dr. Mohammed Bahadori (prescriber) Arthritis Care Center, P.C.  
14904 Jefferson Davis Hwy, Suite 203  
Woodbridge, VA 22192  
(703) 492-6660

**RESPONSE TO REQUEST FOR PRODUCTION NO. 88:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly responds that it will produce documents that can be located through a reasonably diligent search reflecting communication between Lilly and Dr. Bahadori.

**REQUEST FOR PRODUCTION NO. 89:**

Please produce the custodial file, including but not limited to employment agreements, termination agreements, performance reviews, self-reviews, W-2s, and bonus amounts, for each pharmaceutical representative who called upon the following:

- Dr. Mohammed Bahadori (prescriber) Arthritis Care Center, P.C.  
14904 Jefferson Davis Hwy, Suite 203  
Woodbridge, VA 22192  
(703) 492-6660

**RESPONSE TO REQUEST FOR PRODUCTION NO. 89:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 90:**

Please produce all records, entries, or other data from YOUR pharmaceutical representative database, or any other electronic database used to track sales calls to physicians, regarding each and every sales call made to following:

- Dr. Mohammed Bahadori (prescriber) Arthritis Care Center, P.C.  
14904 Jefferson Davis Hwy, Suite 203  
Woodbridge, VA 22192  
(703) 492-6660

**RESPONSE TO REQUEST FOR PRODUCTION NO. 90:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly responds that it will produce documents that can be located through a reasonably diligent search tracking sales calls to Drs. Bahadori related to Cymbalta.

**REQUEST FOR PRODUCTION NO. 91:**

Please produce all DOCUMENTS reflecting any compensation, gifts, payments, honoraria, or consulting fees given by LILLY to the following:

- Dr. Mohammed Bahadori (prescriber) Arthritis Care Center, P.C.  
14904 Jefferson Davis Hwy, Suite 203  
Woodbridge, VA 22192  
(703) 492-6660

**RESPONSE TO REQUEST FOR PRODUCTION NO. 91:**

Lilly responds that there are no documents indicating that Lilly provided compensation to Dr. Bahadori.

**REQUEST FOR PRODUCTION NO. 92:**

Please produce any written agreements, contracts, liability releases, or other legal documents that have been drafted and/or executed between LILLY or any third-party representing LILLY and the following:

- Dr. Mohammed Bahadori (prescriber) Arthritis Care Center, P.C.  
14904 Jefferson Davis Hwy, Suite 203  
Woodbridge, VA 22192  
(703) 492-6660

**RESPONSE TO REQUEST FOR PRODUCTION NO. 92:**

Lilly refers Plaintiff to its objections to this Request.



**REQUEST FOR PRODUCTION NO. 93:**

Please produce all DOCUMENTS, including but not limited to marketing materials, brochures, sales aids, “slim jims,” “skiffs,” clinical trials / medical journal articles, PowerPoint presentations, etc., that were given or shown by LILLY pharmaceutical representatives to the following:

- Dr. Mohammed Bahadori (prescriber) Arthritis Care Center, P.C.  
14904 Jefferson Davis Hwy, Suite 203  
Woodbridge, VA 22192  
(703) 492-6660

**RESPONSE TO REQUEST FOR PRODUCTION NO. 93:**

Subject to and without waiving its Objections to Plaintiff’s First Set of Requests for Production, Lilly responds that the information in its sales database does not indicate which marketing materials or other documents were shown to particular medical professionals.

**REQUEST FOR PRODUCTION NO. 94:**

Please produce all DOCUMENTS reflecting participation in any LILLY-sponsored educational or sales program involving CYMBALTA by the following:

- Dr. Mohammed Bahadori (prescriber) Arthritis Care Center, P.C.  
14904 Jefferson Davis Hwy, Suite 203  
Woodbridge, VA 22192  
(703) 492-6660

**RESPONSE TO REQUEST FOR PRODUCTION NO. 94:**

Lilly responds that there are no documents indicating that Dr. Bahadori attended any Lilly-sponsored program.

**REQUEST FOR PRODUCTION NO. 95:**

Please produce, for the request above, all materials, including but not limited to PowerPoint presentations, syllabus, medical journal articles, summaries, agendas, etc., provided to or shown as part of the LILLY-sponsored program.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 95:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly refers Plaintiff to its response to Request No. 94.

**REQUEST FOR PRODUCTION NO. 96:**

Please produce all records in YOUR possession related to Plaintiff. Please note that this request is in no way limited to medical or psychiatric records, but includes any DOCUMENTS obtained from a third-party by LILLY about the Plaintiff.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 96:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly responds that it will produce records about Plaintiff maintained by Lilly prior to the initiation of this lawsuit that can be located through a reasonably diligent search, but, because Plaintiffs have rejected the sharing of costs relating to medical record collection, Lilly will not be providing records obtained through the litigation medical collection process.

**REQUEST FOR PRODUCTION NO. 97:**

Please produce all DOCUMENTS reflecting any correspondence created in collecting the records described in the above request.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 97:**

Lilly refers Plaintiff to its objections to this Request.

**VII. OTHER REQUESTS**

**REQUEST FOR PRODUCTION NO. 98:**

Please produce all DOCUMENTS identified in YOUR answers to all of Plaintiff's Interrogatories.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 98:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 99:**

Please produce all DOCUMENTS from which YOU obtained answers in responding to all of Plaintiff's Interrogatories.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 99:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 100:**

Please produce the custodial file, including but not limited to employment agreements, termination agreements, performance reviews, self-reviews, W-2s, and bonus amounts, for each individual presented by LILLY as a person most knowledgeable under Federal Rule of Civil Procedure 30(b)(6).

**RESPONSE TO REQUEST FOR PRODUCTION NO. 100:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 101:**

Please produce all electronic mail ("email") for the individuals presented by LILLY as a person most knowledgeable under Federal Rule of Civil Procedure 30(b)(6), whether internal or

external and whether on LILLY's current computer operating system, on individual employees' laptop computers, or archive systems, which contain at least one of the following terms:

**Cy!, dulo!, Ariclaim, Xeristar, Yentreve, Duzela, Dulane, Cymgen, Prozac, Fluox!, Paxil, Parox!, Zoloft, Sertra!, Celexa, Citalop!, Lexapro, Escitalop!, Effexor, venlafa!, Pristiq, desvenlafax!, milnacipr!, levomilnacipr!, SSRI!, SNRI!, or anti!,**

*and* at least one of the following terms:

**DEAE!, discon!, withd!, taper!, cold w/1turkey, addict!, habit!, paresth!, zap!, electric w/4 shock, dizz!, Rosenbaum, Schatzberg, Glenmullen, half-life, "missed dose," downregu!, "greater than or equal to," Perahia, enteric, or time-release.**

**RESPONSE TO REQUEST FOR PRODUCTION NO. 101:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 102:**

Please produce all DOCUMENTS in LILLY's possession, custody or control concerning any governmental investigations of LILLY in relation to CYMBALTA and, in any way, with WITHDRAWAL.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 102:**

Lilly is not aware of any governmental investigations of Lilly in relation to Cymbalta and discontinuation symptoms.

**REQUEST FOR PRODUCTION NO. 103:**

With respect to Lilly's Patient Assistance and/or Lilly Cares Program for CYMBALTA, please produce all documents regarding Lilly's decision to establish the program; its structure

and budget; its criteria for deciding which patients qualify for the program; and any complaints, questions, or comments received from participants, physicians, or pharmacies.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 103:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR PRODUCTION NO. 104:**

Please produce all DOCUMENTS pertaining to Lilly's provision of CYMBALTA to Plaintiff, if applicable, as part of Lilly's Patient Assistance and/or Lilly Cares program.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 104:**

Lilly responds that it has no records indicating that Plaintiff participated in LillyCares, and that Patient Assistance is not available for Cymbalta.

**REQUEST FOR PRODUCTION NO. 105:**

Please produce all Corporate Integrity Agreements LILLY has entered into with any government for any reason.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 105:**

Subject to and without waiving its Objections to Plaintiff's First Set of Requests for Production, Lilly refers Plaintiff to Lilly's corporate integrity agreement, which publicly available at <http://www.lilly.com/Documents/CIA.pdf>

Respectfully Submitted,

Dated: March 9, 2015

By:                     /s/                      
Jeffrey T. Bozman (83679)  
Covington & Burling LLP  
One CityCenter  
850 Tenth Street, NW  
Washington, DC 20001  
Tel: (202) 662-5829  
Fax: (202) 778-5829  
*Counsel for Eli Lilly and Company*

**CERTIFICATE OF SERVICE**

I, Jeffrey T. Bozman, hereby certify that on the 9th day of March, 2015, I have served Plaintiff's counsel in this action with a copy of Defendant's Objections to Plaintiff's First Set of Requests for Production by mailing a copy of the same by United States Mail, postage prepaid, and electronic mail to the following address:

Peter A. Miller  
**Miller Legal LLC**  
175 S. Pantops Drive, Third Floor  
Charlottesville, VA 2291  
Telephone (434) 529-6909  
Facsimile (888) 830-1488  
PMiller@MillerLegalLLC.com  
*Counsel for Gilda Hagan-Brown*

Dated: March 9, 2015

By:                     /s/                      
Jeffrey T. Bozman (83679)  
Covington & Burling LLP  
One CityCenter  
850 Tenth Street, NW  
Washington, DC 20001  
Tel: (202) 662-5829  
Fax: (202) 778-5829  
*Counsel for Eli Lilly and Company*

## Exhibit 5-A



**UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF VIRGINIA  
ALEXANDRIA DIVISION**

GILDA HAGAN-BROWN

Plaintiff,

v.

ELI LILLY AND COMPANY, an Indiana  
corporation,

Defendant.

CASE NO.: 1:14-CV-01614-AJT-JFA

**PLAINTIFF'S FIRST SET OF REQUESTS FOR ADMISSION**

**PROPOUNDING PARTY:** Plaintiff, Gilda Hagan-Brown

**RESPONDING PARTY:** Defendant Eli Lilly and Company

**SET NO.:** ONE

Plaintiff Gilda Hagan- Brown, by and through her attorneys, and pursuant to Federal Rule of Civil Procedure 26 and 36 request that Defendant Eli Lilly and Company (“Lilly”) admit or deny following statements of fact, application of law to fact, and opinions about either, separately and fully in writing and under oath within thirty (30) days of service.

**DEFINITIONS**

1. ““ALL” means “any and all” and the word “any” means “any and all.”
2. The term “CYMBALTA” means duloxetine hydrochloride, including any other name or trademark under which it is sold, domestically *or* abroad, marketed or produced, including products sold, marketed, or produced by others if they do so with your permission, at your request, at your direction, with your acquiescence, and/or if you gain any benefit from their sales, marketing, or distribution.

3. The term “COMMUNICATION” means and refers to every method and manner of transmitting or receiving data, opinions, thoughts, inquiries, representations and other information, whether orally, in writing, electronically, or otherwise, between two or more persons or entities. Communications include drafts and other written information intended for communicating to another person, even if not ultimately transmitted to or received by another person.

4. The term “IDENTIFY” (in reference to a person) means to state, to the extent known, the person’s full name, present or last known address, telephone number, company title (to the extent applicable), and whether or not the person is currently an employee of LILLY (to the extent applicable).

5. The terms “CONCERNING,” “RELATING,” and/or “REGARDING” mean containing, alluding to, responding to, commenting upon, discussing, explaining, mentioning, analyzing, constituting, memorializing, comprising, repeating, incorporating, confirming, listing, evidencing, setting forth, summarizing, or characterizing, either directly or indirectly, in whole or in part.

6. The term “DEAE” means Discontinuation Emergent Adverse Event, and refers to any possible side effects or symptoms relating to discontinuing, withdrawing, or tapering from the use, consumption, or treatment with Cymbalta.

7. The term “WITHDRAWAL” includes discontinuation or tapering, as well as DEAEs, withdrawal symptoms, and any side effects of withdrawing, discontinuing, or tapering from CYMBALTA.

8. The term “DOCUMENT” shall have the broadest meaning possible under Rule 34 of the Federal Rules of Civil Procedure and includes all originals and drafts, in any and all

languages, of any nature whatsoever, in your possession, custody or control, regardless of where located, and include, but are not limited to, letters, correspondence, logs, drafts, contracts, prospective contracts, agreements, reports, records, studies, surveys, resolutions, tabulations, notes, summaries, memoranda, Electronically Stored Information (“ESI”), electronic mail (“email”), calendar or diary entries, handwritten notes, working papers, work sheets, spread sheets, diagrams, minutes of meetings, agendas, bulletins, periodicals, circulars, advertisements, notices, announcements, invoices, statements, checks (front and back), bank statements, ledgers, orders, vouchers, instructions, drawings, charts, graphs, manuals, brochures, pamphlets, schedules, telegrams, teletypes, photographs, audio tapes, voice-mail messages, videotapes, electronic recordings, facsimile transmissions, and information of whatever kind either stored on computers, including computer disks, hard drives and other media, or contained in any computer or information retrieval devices.

9. The terms “ELI LILLY,” “LILLY,” “YOU” or “YOUR” refer to Eli LILLY and Company, its respective officers, directors, employees, representatives, subsidiaries, and affiliates thereof, as well as all persons acting for, on behalf of, or in concert with Eli LILLY and Company’s behalf, including agents, attorneys, accountants, and investigators.

10. The term “FDA” means the United States Food & Drug Administration.

11. The term “INCLUDING” means “including, but not limited to.”

12. The term “LABEL” refers to the official prescribing information for the drug, including but not limited to the product insert and medication guides approved by the FDA or other foreign regulatory bodies.

13. The term “MEDICAL PROFESSIONAL” includes healthcare providers, prescribing doctors, non-prescribing doctors, physicians, pharmacists, nurses, and other

individuals who provide healthcare services.

14. The term “PERAHIA ARTICLE” refers to David G. Perahia, *et al.*, *Symptoms Following Abrupt Discontinuation of Duloxetine Treatment in Patients with Major Depressive Disorder*, 89 J. Affective Disorders 207-12 (2005).

15. The term “SNRI” means serotonin norepinephrine reuptake inhibitor.

16. The term “SSRI” means selective serotonin reuptake inhibitor.

17. The use of the terms “or,” “and,” and “and/or” should be construed conjunctively and disjunctively for the broadest possible meaning.

18. The term “person” or “people” includes individuals, corporations, partnerships, associations, and other bodies and entities, as well as their representatives, agents, employees and attorneys.

19. The terms “research,” “study,” or “analysis,” when used as a noun mean and refer to any research, analysis, study, report, evaluation or assessment. The term research when used as a verb means to research, analyze, study, report, evaluate, or assess.

20. The term “use” means to “employ something for a purpose,” “to do something habitually,” “to consume something,” “to manipulate,” “to benefit from,” as well as to allow others to “use,” or acquiesce in others’ “use.”

21. The singular use of any term or phrase includes its plural, and the plural of any term or phrase includes its singular.

22. The use of any tense of any verb shall also include within its meaning all other tenses of that verb.

### **INSTRUCTIONS**

If a matter is not admitted, the answer must specifically deny it or state in detail why

YOU cannot truthfully admit or deny it. A denial must fairly respond to the substance of the matter. When, in good-faith, YOUR answer requires a qualification or YOU can only deny part of a matter, the answer must specify the part admitted and qualify or deny the rest. YOU may assert lack of knowledge or information as a reason for failing to admit or deny only if YOU clearly state that YOU have made reasonable inquiry and that the information YOU possess or can readily obtain is insufficient to enable YOU to admit or deny.

### **REQUESTS FOR ADMISSION**

#### **REQUEST FOR PRODUCTION NO. 1:**

Admit that the gradual or sudden discontinuation of CYMBALTA can cause adverse symptoms resulting from the discontinuation of CYMBALTA.

#### **REQUEST FOR PRODUCTION NO. 2:**

Admit that the abrupt discontinuation of a daily dose of 20 mg of CYMBALTA can cause adverse symptoms resulting from the discontinuation of CYMBALTA.

#### **REQUEST FOR PRODUCTION NO. 3:**

Admit that the abrupt discontinuation of a daily dose of 30 mg of CYMBALTA can cause adverse symptoms resulting from the discontinuation of CYMBALTA.

#### **REQUEST FOR PRODUCTION NO. 4:**

Admit that the abrupt discontinuation of a daily dose of 40 mg of CYMBALTA can cause adverse symptoms resulting from the discontinuation of CYMBALTA.

#### **REQUEST FOR PRODUCTION NO. 5:**

Admit that the abrupt discontinuation of a daily dose of 60 mg of CYMBALTA can cause adverse symptoms resulting from the discontinuation of CYMBALTA.

**REQUEST FOR PRODUCTION NO. 6:**

Admit that CYMBALTA's risk of causing adverse symptoms resulting from discontinuation of CYMBALTA is something a reasonable prescriber would consider important in deciding whether to prescribe the medication.

**REQUEST FOR PRODUCTION NO. 7:**

Admit that CYMBALTA's risk of causing adverse symptoms resulting from discontinuation of CYMBALTA is something a reasonable person would consider important in deciding whether to purchase and ingest the medication.

**REQUEST FOR PRODUCTION NO. 8:**

Admit that the gradual or sudden discontinuation of CYMBALTA can cause nausea.

**REQUEST FOR PRODUCTION NO. 9:**

Admit that the gradual or sudden discontinuation of CYMBALTA can cause headaches.

**REQUEST FOR PRODUCTION NO. 10:**

Admit that the gradual or sudden discontinuation of CYMBALTA can cause paresthesia.

**REQUEST FOR PRODUCTION NO. 11:**

Admit that the gradual or sudden discontinuation of CYMBALTA can cause nightmares.

**REQUEST FOR PRODUCTION NO. 12:**

Admit that the gradual or sudden discontinuation of CYMBALTA can cause insomnia.

**REQUEST FOR PRODUCTION NO. 13:**

Admit that the gradual or sudden discontinuation of CYMBALTA can cause anxiety.

**REQUEST FOR PRODUCTION NO. 14:**

Admit that the gradual or sudden discontinuation of CYMBALTA can cause hyperhidrosis.

**REQUEST FOR PRODUCTION NO. 15:**

Admit that the gradual or sudden discontinuation of CYMBALTA can cause sensory disturbances.

**REQUEST FOR PRODUCTION NO. 16:**

Admit that the gradual or sudden discontinuation of CYMBALTA can cause suicidal ideation.

**REQUEST FOR PRODUCTION NO. 17:**

Admit that the gradual or sudden discontinuation of CYMBALTA can cause seizures.

**REQUEST FOR PRODUCTION NO. 18:**

Admit that, between 2004 and 2011, LILLY obtained over \$17 billion in revenue from the sale of CYMBALTA within the United States.

**REQUEST FOR PRODUCTION NO. 19:**

Admit that CYMBALTA has a shorter half-life than Prozac.

**REQUEST FOR PRODUCTION NO. 20:**

Admit that CYMBALTA has a shorter half-life than Paxil.

**REQUEST FOR PRODUCTION NO. 21:**

Admit that CYMBALTA has a shorter half-life than Zoloft.

**REQUEST FOR PRODUCTION NO. 22:**

Admit that CYMBALTA has a shorter half-life than Celexa.

**REQUEST FOR PRODUCTION NO. 23:**

Admit that CYMBALTA has a shorter half-life than Lexapro.

**REQUEST FOR PRODUCTION NO. 24:**

Admit that Effexor has a shorter half-life than CYMBALTA.

**REQUEST FOR PRODUCTION NO. 25:**

Admit that the shorter the half-life of an SSRI or SNRI, the more frequent the occurrences of WITHDRAWAL.

**REQUEST FOR PRODUCTION NO. 26:**

Admit that Daniel Kajdasz was an employee of LILLY when the PERAHIA ARTICLE was published.

**REQUEST FOR PRODUCTION NO. 27:**

Admit that Durisala Desaiiah was an employee of LILLY when the PERAHIA ARTICLE was published.

**REQUEST FOR PRODUCTION NO. 28:**

Admit that Peter Haddad has received payments from LILLY for attending advisory boards, lecturing, and consultancy work.

**REQUEST FOR PRODUCTION NO. 29:**

Admit that YOU never instructed YOUR sales force to distribute the PERAHIA ARTICLE to physicians when it was published in 2005.

**REQUEST FOR PRODUCTION NO. 30:**

Admit that, in the six acute treatment placebo controlled trials identified in the PERAHIA ARTICLE, 44.3% of patients receiving CYMBALTA reported at least one discontinuation-emergent adverse event.

**REQUEST FOR PRODUCTION NO. 31:**

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**REQUEST FOR PRODUCTION NO. 32:**

Admit that, in the six acute treatment placebo controlled trials identified in the PERAHIA ARTICLE, 3.1% of patients in the CYMBALTA treatment groups withdrew from the studies because of a discontinuation-emergent adverse event.

**REQUEST FOR PRODUCTION NO. 33:**

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**REQUEST FOR PRODUCTION NO. 34:**

Admit that, in the six acute treatment placebo controlled trials identified in the PERAHIA ARTICLE, of the discontinuation-emergent adverse events reported, 53.7% remained unresolved after two weeks.

**REQUEST FOR PRODUCTION NO. 35:**

Admit that, in a fifty-two week open-label clinical trial for CYMBALTA identified in the PERAHIA ARTICLE, 50.8% of patients suffered at least one discontinuation-emergent adverse event.

**REQUEST FOR PRODUCTION NO. 36:**

Admit that, in a fifty-two week open-label clinical trial for CYMBALTA identified in the PERAHIA ARTICLE, of the discontinuation-emergent adverse events reported, 46.3% were moderate and 17.2% were severe.

**REQUEST FOR PRODUCTION NO. 37:**

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resolved after two weeks.

**REQUEST FOR PRODUCTION NO. 38:**

Admit that LILLY does not know how long it took for the discontinuation-emergent adverse events discussed in the PERAHIA ARTICLE to fully resolve.

**REQUEST FOR PRODUCTION NO. 39:**

Admit that the work conducted in the PERAHIA ARTICLE was funded by LILLY.

**REQUEST FOR PRODUCTION NO. 40:**

Admit that the DEAEs measured in the PERAHIA ARTICLE were assessed by means of spontaneous reports rather than a symptom checklist.

**REQUEST FOR PRODUCTION NO. 41:**

Admit that use of a symptom checklist, instead of spontaneous reports, would be expected to produce higher incidence rates of DEAEs in the PERAHIA ARTICLE.

**REQUEST FOR PRODUCTION NO. 42:**

Admit that LILLY sponsored the clinical trial by Jerrold Rosenbaum et al, *Selective Serotonin Reuptake Inhibitor Discontinuation Syndrome: A Randomized Clinical Trial*, 44 BIOLOGICAL PSYCHIATRY 2, 77-87 (1998).

**REQUEST FOR PRODUCTION NO. 43:**

Admit that, in Jerrold Rosenbaum et al, *Selective Serotonin Reuptake Inhibitor Discontinuation Syndrome: A Randomized Clinical Trial*, 44 BIOLOGICAL PSYCHIATRY 2, 77-87 (1998), the researchers used a symptom checklist to tabulate DEAEs / withdrawal symptoms.

**REQUEST FOR PRODUCTION NO. 44:**

Admit that the information contained in the European Medicines Agency Summary of Product Information for CYMBALTA is accurate and true.

**REQUEST FOR PRODUCTION NO. 45:**

Admit that, in clinical trials, adverse events seen on abrupt treatment discontinuation of CYMBALTA occurred in approximately 45% of patients treated with CYMBALTA.

**REQUEST FOR PRODUCTION NO. 46:**

Admit that the following statement appears in the European Medicines Agency Summary of Product Information for CYMBALTA: “In clinical trials adverse events seen on abrupt treatment discontinuation occurred in approximately 45% of patients treated with Cymbalta and 23% of patients taking placebo.”

**REQUEST FOR PRODUCTION NO. 47:**

Admit that the following statement does not appear on the CYMBALTA LABEL: “In clinical trials adverse events seen on abrupt treatment discontinuation occurred in approximately 45% of patients treated with Cymbalta and 23% of patients taking placebo.”

**REQUEST FOR PRODUCTION NO. 48:**

Admit that at no time has LILLY’s direct-to-consumer advertising, i.e., television, newspapers, magazines, and/or radio, warned patients that abrupt discontinuation of CYMBALTA occurred in approximately 45% of patients treated with CYMBALTA.

**REQUEST FOR PRODUCTION NO. 49:**

Admit that the following statement appears in the European Medicines Agency Summary of Product Information for CYMBALTA: “It is therefore advised that duloxetine should be gradually tapered when discontinuing treatment over a period of no less than 2 weeks, according to the patient’s needs (see section 4.2).”

**REQUEST FOR PRODUCTION NO. 50:**

Admit that the CYMBALTA LABEL does not state that CYMBALTA should be

gradually tapered “over a period of no less than 2 weeks[.]”

**REQUEST FOR PRODUCTION NO. 51:**

Admit that the European Medicines Agency Summary of Product Information for CYMBALTA refers to “discontinuation-emergent adverse events” as “withdrawal symptoms.”

**REQUEST FOR PRODUCTION NO. 52:**

Admit that the following statement appears in the European Medicines Agency Summary of Product Information for CYMBALTA: Withdrawal symptoms “may be prolonged (2-3 months or more).”

**REQUEST FOR PRODUCTION NO. 53:**

Admit that the CYMBALTA LABEL does not estimate how long discontinuation-emergent adverse events will likely take to resolve following abrupt or tapered discontinuation of CYMBALTA.

**REQUEST FOR PRODUCTION NO. 54:**

Admit that the CYMBALTA LABEL does not indicate that some individuals may have withdrawal symptoms for 2-3 months or more.

**REQUEST FOR PRODUCTION NO. 55:**

Admit that the CYMBALTA LABEL does not specify what percentage of patients will likely experience at least one discontinuation-emergent adverse event upon abrupt or tapered discontinuation of CYMBALTA.

**REQUEST FOR PRODUCTION NO. 56:**

Admit that YOU, not the FDA, bear responsibility for the content of the CYMBALTA LABEL at all times.

**REQUEST FOR PRODUCTION NO. 57:**

Admit that the smallest approved dose for CYMBALTA is 20 mg.

**REQUEST FOR PRODUCTION NO. 58:**

Admit that CYMBALTA has an elimination half-life of about 12 hours (range 8 to 17 hours).

**REQUEST FOR PRODUCTION NO. 59:**

Admit that CYMBALTA should be swallowed whole and should not be chewed or crushed.

**REQUEST FOR PRODUCTION NO. 60:**

Admit that the CYMBALTA capsule should not be opened and its contents sprinkled on food or mixed with liquids.

**REQUEST FOR PRODUCTION NO. 61:**

Admit that opening a CYMBALTA capsule, or crushing or chewing the CYMBALTA capsule, might affect its enteric coating.

Dated: February 4, 2015

Respectfully submitted,

**MILLER LEGAL, LLC**

/s/ Brielle M. Hunt

Brielle M. Hunt  
Miller Legal, LLC  
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-and-

**BAUM HEDLUND ARISTEI & GOLDMAN,  
P.C.**

/s/ R. Brent Wisner

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Email: [rbwisner@baumgedlundlaw.com](mailto:rbwisner@baumgedlundlaw.com)

**CERTIFICATE OF SERVICE**

I hereby certify that on this 4<sup>th</sup> day of February, 2015, a true and correct copy of the foregoing **PLAINTIFF'S FIRST SET OF REQUESTS FOR ADMISSION** was served via Electronic Mail, upon the following:

Jeffrey Todd Bozman  
Brett C. Reynolds (pro hac vice)  
Michael X. Imbroscio (pro hac vice)  
Phyllis A. Jones (pro hac vice)  
**COVINGTON & BURLING LLP**  
One City Center  
850 Tenth Street, NW  
Washington, DC 20001  
Email: [jbozman@cov.com](mailto:jbozman@cov.com)  
Email: [breynolds@cov.com](mailto:breynolds@cov.com)  
Email: [mimbrosio@cov.com](mailto:mimbrosio@cov.com)  
Email: [pajones@cov.com](mailto:pajones@cov.com)

*Attorneys for Eli Lilly and Company*

/s/

\_\_\_\_\_  
Samantha Jison

## Exhibit 5-B



**UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF VIRGINIA  
ALEXANDRIA DIVISION**

GILDA HAGAN-BROWN

Plaintiff,

v.

ELI LILLY AND COMPANY, an Indiana  
corporation,

Defendant.

CASE NO.: 1:14-CV-01614-AJT-JFA

**DEFENDANT’S OBJECTIONS TO PLAINTIFF’S AMENDED FIRST SET OF  
REQUESTS FOR ADMISSION**

Pursuant to Federal Rule of Civil Procedure 36, Defendant Eli Lilly and Company (“Defendant” or “Lilly”) hereby submits its objections to Plaintiff’s Amended First Set of Requests for Admission, as follows:

**OBJECTIONS TO DEFINITIONS AND INSTRUCTIONS**

1. Lilly objects to the definitions of the terms “ELI LILLY”, “LILLY”, “YOU”, and “YOUR” to the extent that they seek to extend these definitions to persons or entities other than the named Defendant in this litigation, Eli Lilly and Company, and purport to call for information or documents that are not in the possession, custody, or control of Eli Lilly and Company. For purposes of its objections and responses, Lilly will define “ELI LILLY”, “LILLY”, “YOU”, and “YOUR” to mean Eli Lilly and Company. Lilly will limit its responses to information and documents that are in the possession, custody, or control of Eli Lilly and Company.

2. Lilly objects to the definition of “DOCUMENT” to the extent that it imposes

obligations on Lilly beyond those in the Federal Rules of Civil Procedure.

**SPECIFIC OBJECTIONS TO REQUESTS FOR ADMISSION**

**REQUEST FOR ADMISSION NO. 1:**

Admit that the gradual or sudden discontinuation of CYMBALTA can cause adverse symptoms resulting from the discontinuation of CYMBALTA.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 1:**

Lilly objects to this Request for Admission because it is phrased as a tautology and the use of the term “cause” is vague and ambiguous as to the standard for causality. Lilly will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 2:**

Admit that the abrupt discontinuation of a daily dose of 20 mg of CYMBALTA can cause adverse symptoms resulting from the discontinuation of CYMBALTA.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 2:**

Lilly objects to this Request for Admission because it is phrased as a tautology and the use of the term “cause” is vague and ambiguous as to the standard for causality. Lilly will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 3:**

Admit that the abrupt discontinuation of a daily dose of 30 mg of CYMBALTA can cause adverse symptoms resulting from the discontinuation of CYMBALTA.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 3:**

Lilly objects to this Request for Admission because it is phrased as a tautology and the use of the term “cause” is vague and ambiguous as to the standard for causality. Lilly will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 4:**

Admit that the abrupt discontinuation of a daily dose of 40 mg of CYMBALTA can cause adverse symptoms resulting from the discontinuation of CYMBALTA.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 4:**

Lilly objects to this Request for Admission because it is phrased as a tautology and the use of the term “cause” is vague and ambiguous as to the standard for causality. Lilly will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 5:**

Admit that the abrupt discontinuation of a daily dose of 60 mg of CYMBALTA can cause adverse symptoms resulting from the discontinuation of CYMBALTA.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 5:**

Lilly objects to this Request for Admission because it is phrased as a tautology and the use of the term “cause” is vague and ambiguous as to the standard for causality. Lilly will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 6:**

Admit that CYMBALTA's risk of causing adverse symptoms resulting from discontinuation of CYMBALTA is something a reasonable prescriber would consider important in deciding whether to prescribe the medication.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 6:**

Lilly objects to this Request for Admission because the use of the term "important" is vague and ambiguous, and because the request as phrased is not subject to a simple "Admit" or "Deny" response because of the complex and individualized set of considerations that a medical provider and a patient must take into account when considering the nature of the underlying psychiatric or disease or pain condition and the range of possible medical treatments, especially given the varied and individualized efficacy for a given medicine. Lilly will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 7:**

Admit that CYMBALTA's risk of causing adverse symptoms resulting from discontinuation of CYMBALTA is something a reasonable person would consider important in deciding whether to purchase and ingest the medication.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 7:**

Lilly objects to this Request for Admission because the use of the term "important" is vague and ambiguous, and because the request as phrased is not subject to a simple "Admit" or "Deny" response because of the complex and individualized set of considerations that a medical provider and a patient must take into account when considering the nature of the underlying psychiatric or disease or pain condition and the range of possible medical treatments, especially

given the varied and individualized efficacy for a given medicine. Lilly will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 8:**

Admit that the gradual or sudden discontinuation of CYMBALTA can cause nausea.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 8:**

Lilly objects to this Request for Admission because the use of the term “cause” is vague and ambiguous as to the standard for causality. Lilly will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 9:**

Admit that the gradual or sudden discontinuation of CYMBALTA can cause headaches.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 9:**

Lilly objects to this Request for Admission because the use of the term “cause” is vague and ambiguous as to the standard for causality. Lilly will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 10:**

Admit that the gradual or sudden discontinuation of CYMBALTA can cause paresthesia.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 10:**

Lilly objects to this Request for Admission because the use of the term “cause” is vague and ambiguous as to the standard for causality. Lilly will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 11:**

Admit that the gradual or sudden discontinuation of CYMBALTA can cause nightmares.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 11:**

Lilly objects to this Request for Admission because the use of the term “cause” is vague and ambiguous as to the standard for causality. Lilly will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 12:**

Admit that the gradual or sudden discontinuation of CYMBALTA can cause insomnia.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 12:**

Lilly objects to this Request for Admission because the use of the term “cause” is vague and ambiguous as to the standard for causality. Lilly will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 13:**

Admit that the gradual or sudden discontinuation of CYMBALTA can cause anxiety.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 13:**

Lilly objects to this Request for Admission because the use of the term “cause” is vague and ambiguous as to the standard for causality. Lilly will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 14:**

Admit that the gradual or sudden discontinuation of CYMBALTA can cause hyperhidrosis.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 14:**

Lilly objects to this Request for Admission because the use of the term “cause” is vague and ambiguous as to the standard for causality. Lilly will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 15:**

Admit that the gradual or sudden discontinuation of CYMBALTA can cause sensory disturbances.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 15:**

Lilly objects to this Request for Admission because the use of the term “cause” is vague and ambiguous as to the standard for causality. Lilly will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 16:**

Admit that the gradual or sudden discontinuation of CYMBALTA can cause suicidal ideation.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 16:**

Lilly objects to this Request for Admission because the use of the term “cause” is vague and ambiguous as to the standard for causality. Lilly will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 17:**

Admit that the gradual or sudden discontinuation of CYMBALTA can cause seizures.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 17:**

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**REQUEST FOR ADMISSION NO. 18:**

Admit that, between 2004 and 2011, LILLY obtained over \$17 billion in revenue from the sale of CYMBALTA within the United States.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 18:**

Lilly has no objection and will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 19:**

Admit that CYMBALTA has a shorter half-life than Prozac.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 19:**

Lilly has no objection and will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 20:**

Admit that CYMBALTA has a shorter half-life than Paxil.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 20:**

Lilly has no objection and will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.



**REQUEST FOR ADMISSION NO. 21:**

Admit that CYMBALTA has a shorter half-life than Zoloft.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 21:**

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**REQUEST FOR ADMISSION NO. 22:**

Admit that CYMBALTA has a shorter half-life than Celexa.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 22:**

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**REQUEST FOR ADMISSION NO. 23:**

Admit that CYMBALTA has a shorter half-life than Lexapro.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 23:**

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**REQUEST FOR ADMISSION NO. 24:**

Admit that Effexor has a shorter half-life than CYMBALTA.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 24:**

Lilly has no objection and will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 25:**

Admit that the shorter the half-life of an SSRI or SNRI, the more frequent the occurrences of WITHDRAWAL.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 25:**

Lilly objects to this Request for Admission because its use of the term “occurrences of WITHDRAWAL” is vague and ambiguous given Plaintiff’s definition of “WITHDRAWAL.” Lilly will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 26:**

Admit that Daniel Kajdasz was an employee of LILLY when the PERAHIA ARTICLE was published.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 26:**

Lilly has no objection and will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 27:**

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Admit that Peter Haddad has received payments from LILLY for attending advisory boards, lecturing, and consultancy work.

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Admit that, in the six acute treatment placebo controlled trials identified in the PERAHIA ARTICLE, 44.3% of patients receiving CYMBALTA reported at least one discontinuation-emergent adverse event.

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Lilly objects to this Request to the extent it simply seeks Lilly to affirm statements from a published article, which is not an appropriate use of Requests for Admission under Rule 36. Lilly will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

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**OBJECTIONS TO REQUEST FOR ADMISSION NO. 32:**

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**OBJECTIONS TO REQUEST FOR ADMISSION NO. 37:**

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Lilly will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 38:**

Admit that LILLY does not know how long it took for the discontinuation-emergent adverse events discussed in the PERAHIA ARTICLE to fully resolve.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 38:**

Lilly objects to this Request for Admission because its use of the term “fully” is vague and ambiguous, and further that the article referenced reported on a large number of trials involving hundreds of subjects and thus it is impossible to “Admit” or “Deny” such a blanket statement. Lilly will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 39:**

Admit that the work conducted in the PERAHIA ARTICLE was funded by LILLY.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 39:**

Lilly objects to this Request for Admission because its use of the phrase “work conducted” is vague and ambiguous. Lilly will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36..

**REQUEST FOR ADMISSION NO. 40:**

Admit that the DEAEs measured in the PERAHIA ARTICLE were assessed by means of spontaneous reports rather than a symptom checklist.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 40:**

Lilly objects to this Request for Admission to the extent it mischaracterizes Lilly’s assessment of DEAEs in clinical trials as not systematically evaluated, and because it simply seeks Lilly to affirm statements from a published article, which is not an appropriate use of

Requests for Admission under Rule 36. Lilly will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 41:**

Admit that use of a symptom checklist, instead of spontaneous reports, would be expected to produce higher incidence rates of DEAEs in the PERAHIA ARTICLE.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 41:**

Lilly objects to this Request for Admission to the extent it implies that the use of a symptom checklist to assess DEAEs in clinical trials would result in a more accurate measurement of the incidence of DEAEs than other methods of assessing DEAEs. Lilly will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 42:**

Admit that LILLY sponsored the clinical trial by Jerrold Rosenbaum et al, Selective Serotonin Reuptake Inhibitor Discontinuation Syndrome: A Randomized Clinical Trial, 44 BIOLOGICAL PSYCHIATRY 2, 77-87 (1998).

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 42:**

Lilly has no objection and will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 43:**

Admit that, in Jerrold Rosenbaum et al, Selective Serotonin Reuptake Inhibitor Discontinuation Syndrome: A Randomized Clinical Trial, 44 BIOLOGICAL PSYCHIATRY 2,



77-87 (1998), the researchers used a symptom checklist to tabulate DEAEs / withdrawal symptoms.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 43:**

Lilly has no objection and will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 44:**

Admit that the information contained in the European Medicines Agency Summary of Product Information for CYMBALTA is accurate and true.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 44:**

Lilly objects to this Request for Admission to the extent it implies that the information contained in the European Medicines Agency Summary of Product Characteristics for Cymbalta is the most comprehensive source of information concerning Cymbalta. Lilly will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 45:**

Admit that, in clinical trials, adverse events seen on abrupt treatment discontinuation of CYMBALTA occurred in approximately 45% of patients treated with CYMBALTA.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 45:**

Lilly has no objection and will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 46:**

Admit that the following statement appears in the European Medicines Agency Summary of Product Information for CYMBALTA: “In clinical trials adverse events seen on abrupt treatment discontinuation occurred in approximately 45% of patients treated with Cymbalta and 23% of patients taking placebo.”

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 46:**

Lilly has no objection and will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 47:**

Admit that the following statement does not appear on the CYMBALTA LABEL: “In clinical trials adverse events seen on abrupt treatment discontinuation occurred in approximately 45% of patients treated with Cymbalta and 23% of patients taking placebo.”

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 47:**

Lilly objects to this Request for Admission because its use of the term “LABEL” is vague and ambiguous given Plaintiff’s definition of “LABEL.”

**REQUEST FOR ADMISSION NO. 48:**

Admit that at no time has LILLY’s direct-to-consumer advertising, i.e., television, newspapers, magazines, and/or radio, warned patients that abrupt discontinuation of CYMBALTA occurred in approximately 45% of patients treated with CYMBALTA.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 48:**

Lilly objects to this Request as nonsensical and cannot reasonably respond under Rule 36.

**REQUEST FOR ADMISSION NO. 49:**

Admit that the following statement appears in the European Medicines Agency Summary of Product Information for CYMBALTA: “It is therefore advised that duloxetine should be gradually tapered when discontinuing treatment over a period of no less than 2 weeks, according to the patient’s needs (see section 4.2).”

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 49:**

Lilly has no objection and will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 50:**

Admit that the CYMBALTA LABEL does not state that CYMBALTA should be gradually tapered “over a period of no less than 2 weeks[.]”

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 50:**

Lilly objects to this Request for Admission because its use of the term “LABEL” is vague and ambiguous given Plaintiff’s definition of “LABEL.”

**REQUEST FOR ADMISSION NO. 51:**

Admit that the European Medicines Agency Summary of Product Information for CYMBALTA refers to “discontinuation-emergent adverse events” as “withdrawal symptoms.”

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 51:**

Lilly has no objection and will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 52:**

Admit that the following statement appears in the European Medicines Agency Summary of Product Information for CYMBALTA: Withdrawal symptoms “may be prolonged (2-3 months or more).”

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 52:**

Lilly has no objection and will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 53:**

Admit that the CYMBALTA LABEL does not estimate how long discontinuation-emergent adverse events will likely take to resolve following abrupt or tapered discontinuation of CYMBALTA.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 53:**

Lilly objects to this Request for Admission because its use of the term “LABEL” is vague and ambiguous given Plaintiff’s definition of “LABEL.”

**REQUEST FOR ADMISSION NO. 54:**

Admit that the CYMBALTA LABEL does not indicate that some individuals may have withdrawal symptoms for 2-3 months or more.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 54:**

Lilly objects to this Request for Admission because its use of the term “LABEL” is vague and ambiguous given Plaintiff’s definition of “LABEL.”

**REQUEST FOR ADMISSION NO. 55:**

Admit that the CYMBALTA LABEL does not specify what percentage of patients will likely experience at least one discontinuation-emergent adverse event upon abrupt or tapered discontinuation of CYMBALTA.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 55:**

Lilly objects to this Request for Admission because its use of the term “LABEL” is vague and ambiguous given Plaintiff’s definition of “LABEL.”

**REQUEST FOR ADMISSION NO. 56:**

Admit that YOU, not the FDA, bear responsibility for the content of the CYMBALTA LABEL at all times.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 56:**

Lilly objects to this Request for Admission because its use of the term “responsibility” is vague and ambiguous. Lilly further objects to this Request to the extent that it calls for a legal conclusion.

**REQUEST FOR ADMISSION NO. 57:**

Admit that the smallest approved dose for CYMBALTA is 20 mg.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 57:**

Lilly has no objection and will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 58:**

Admit that CYMBALTA has an elimination half-life of about 12 hours (range 8 to 17 hours).

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 58:**

Lilly has no objection and will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 59:**

Admit that CYMBALTA should be swallowed whole and should not be chewed or crushed.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 59:**

Lilly has no objection and will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 60:**

Admit that the CYMBALTA capsule should not be opened and its contents sprinkled on food or mixed with liquids.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 60:**

Lilly has no objection and will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

**REQUEST FOR ADMISSION NO. 61:**

Admit that opening a CYMBALTA capsule, or crushing or chewing the CYMBALTA capsule, might affect its enteric coating.

**OBJECTIONS TO REQUEST FOR ADMISSION NO. 61:**

Lilly has no objection and will make a good faith effort to respond to this request to the extent possible and consistent with the requirements of Rule 36.

Respectfully Submitted,

Dated: February 23, 2015

By: \_\_\_\_\_/s/  
Jeffrey T. Bozman (83679)  
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*Counsel for Eli Lilly and Company*

**CERTIFICATE OF SERVICE**

I, Jeffrey T. Bozman, hereby certify that on the 23rd day of February, 2015, I have served Plaintiff's counsel in this action with a copy of Defendant's Objections to Plaintiffs First Set of Requests for Admission by mailing a copy of the same by United States Mail, postage prepaid, and electronic mail to the following address:

Peter A. Miller  
**Miller Legal LLC**  
175 S. Pantops Drive, Third Floor  
Charlottesville, VA 2291  
Telephone (434) 529-6909  
Facsimile (888) 830-1488  
PMiller@MillerLegalLLC.com  
*Counsel for Gilda Hagan-Brown*

Dated: February 23, 2015

By:                     /s/                      
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*Counsel for Eli Lilly and Company*



## Exhibit 5-C

**UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF VIRGINIA  
ALEXANDRIA DIVISION**

GILDA HAGAN-BROWN

Plaintiff,

v.

ELI LILLY AND COMPANY, an Indiana  
corporation,

Defendant.

CASE NO.: 1:14-CV-01614

**DEFENDANT'S RESPONSES TO PLAINTIFF'S AMENDED FIRST SET OF  
REQUESTS FOR ADMISSION**

Pursuant to Federal Rule of Civil Procedure 36, Defendant Eli Lilly and Company ("Defendant" or "Lilly") hereby submits its responses to Plaintiff's Amended First Set of Requests for Admission, as follows:

**GENERAL STATEMENT**

The following responses are subject to Lilly's Objections to Plaintiff's Amended First Set of Requests for Admission served on February 23, 2015 pursuant to Federal Rule of Civil Procedure 36 and Local Civil Rule 26 and, for the sake of brevity, not repeated herein. Lilly has not fully completed its investigation of the facts relating to this case, its discovery, or its preparation for trial. Both discovery and independent investigation are ongoing. Therefore, all responses contained herein are based solely upon such information and documents as are both presently available and specifically known to Lilly. Lilly reserves the right to supplement these responses as discovery and this investigation proceed. Lilly's responses are in accordance with

the requirements of the Federal Rules of Civil Procedure, the Local Rules, and any applicable Court Orders.

## **RESPONSES TO REQUESTS FOR ADMISSION**

### **REQUEST FOR ADMISSION NO. 1:**

Admit that the gradual or sudden discontinuation of CYMBALTA can cause adverse symptoms resulting from the discontinuation of CYMBALTA.

### **RESPONSE TO REQUEST FOR ADMISSION NO. 1:**

Subject to Lilly's Objections to Plaintiff's Amended Requests for Admissions, Lilly admits that in some patients who are treated with Cymbalta, the gradual or sudden discontinuation of Cymbalta can lead to certain adverse symptoms, as warned in the August 2004 United States Physician Package Insert ("U.S. label") for Cymbalta:

#### **WARNINGS**

...

If the decision has been made to discontinue treatment, medication should be tapered, as rapidly as is feasible, but with recognition that abrupt discontinuation can be associated with certain symptoms (see PRECAUTIONS and DOSAGE AND ADMINISTRATION, Discontinuing Cymbalta (duloxetine hydrochloride), for a description of the risks of discontinuation of Cymbalta).

\* \* \*

#### **PRECAUTIONS**

...

Discontinuation of Treatment with Cymbalta -- Discontinuation symptoms have been systematically evaluated in patients taking Cymbalta. Following abrupt discontinuation in placebo-controlled clinical trials of up to 9-weeks duration, the following symptoms occurred at a rate greater than or equal to 2% and at a significantly higher rate in duloxetine-treated patients compared to those discontinuing from placebo: dizziness; nausea; headache; paresthesia; vomiting; irritability; and nightmare.

During marketing of other SSRIs and SNRIs (serotonin and norepinephrine reuptake inhibitors), there have been spontaneous reports of adverse events occurring upon discontinuation of these drugs, particularly when abrupt, including the following: dysphoric mood, irritability, agitation, dizziness, sensory disturbances (e.g., paresthesias such as electric shock sensations), anxiety, confusion, headache, lethargy, emotional lability, insomnia, hypomania, tinnitus,

and seizures. Although these events are generally self-limiting, some have been reported to be severe.

Patients should be monitored for these symptoms when discontinuing treatment with Cymbalta. A gradual reduction in the dose rather than abrupt cessation is recommended whenever possible. If intolerable symptoms occur following a decrease in the dose or upon discontinuation of treatment, then resuming the previously prescribed dose may be considered. Subsequently, the physician may continue decreasing the dose but at a more gradual rate (see DOSAGE AND ADMINISTRATION).

\* \* \*

## **DOSAGE AND ADMINISTRATION**

...

### **Discontinuing Cymbalta (duloxetine hydrochloride)**

Symptoms associated with discontinuation of Cymbalta and other SSRIs and SNRIs have been reported (see PRECAUTIONS). Patients should be monitored for these symptoms when discontinuing treatment. A gradual reduction in the dose rather than abrupt cessation is recommended whenever possible. If intolerable symptoms occur following a decrease in the dose or upon discontinuation of treatment, then resuming the previously prescribed dose may be considered. Subsequently, the physician may continue decreasing the dose but at a more gradual rate.

This warning has remained largely unchanged since Cymbalta's initial FDA approval for the treatment of Major Depressive Disorder.

## **REQUEST FOR ADMISSION NO. 2:**

Admit that the abrupt discontinuation of a daily dose of 20 mg of CYMBALTA can cause adverse symptoms resulting from the discontinuation of CYMBALTA.

## **RESPONSE TO REQUEST FOR ADMISSION NO. 2:**

Subject to Lilly's Objections to Plaintiff's Amended Requests for Admissions, because Lilly has not comprehensively studied the abrupt discontinuation from the 20 mg/day dose of Cymbalta, and because this low dose is unlikely to present a similar profile than a fully therapeutic dose, denied.

**REQUEST FOR ADMISSION NO. 3:**

Admit that the abrupt discontinuation of a daily dose of 30 mg of CYMBALTA can cause adverse symptoms resulting from the discontinuation of CYMBALTA.

**RESPONSE TO REQUEST FOR ADMISSION NO. 3:**

Subject to Lilly's Objections to Plaintiff's Amended Requests for Admissions, Lilly admits that in some patients who are treated with Cymbalta, the abrupt discontinuation of a 30 mg/day dose of Cymbalta may be associated with certain adverse symptoms, which are listed in Cymbalta's U.S. label, but further notes that many such patients do not experience such symptoms upon discontinuation.

**REQUEST FOR ADMISSION NO. 4:**

Admit that the abrupt discontinuation of a daily dose of 40 mg of CYMBALTA can cause adverse symptoms resulting from the discontinuation of CYMBALTA.

**RESPONSE TO REQUEST FOR ADMISSION NO. 4:**

Subject to Lilly's Objections to Plaintiff's Amended Requests for Admissions, Lilly admits that in some patients who are treated with Cymbalta, the abrupt discontinuation of a 40 mg/day dose of Cymbalta is associated with certain adverse symptoms, which are listed in Cymbalta's U.S. label, but further notes that many such patients do not experience such symptoms upon discontinuation.

**REQUEST FOR ADMISSION NO. 5:**

Admit that the abrupt discontinuation of a daily dose of 60 mg of CYMBALTA can cause adverse symptoms resulting from the discontinuation of CYMBALTA.

**RESPONSE TO REQUEST FOR ADMISSION NO. 5:**

Subject to Lilly's Objections to Plaintiff's Amended Requests for Admissions, Lilly admits that in some patients who are treated with Cymbalta, the abrupt discontinuation of a 60 mg/day dose of Cymbalta is associated with certain adverse symptoms, which are listed in Cymbalta's U.S. label, but further notes that many such patients do not experience such symptoms upon discontinuation.

**REQUEST FOR ADMISSION NO. 6:**

Admit that CYMBALTA's risk of causing adverse symptoms resulting from discontinuation of CYMBALTA is something a reasonable prescriber would consider important in deciding whether to prescribe the medication.

**RESPONSE TO REQUEST FOR ADMISSION NO. 6:**

Subject to Lilly's Objections to Plaintiff's Amended Requests for Admissions, Lilly admits that the risk of the occurrence of adverse symptoms upon discontinuation from an antidepressant like Cymbalta, which is stated in Cymbalta's U.S. label, is one of the many pieces of information that form part of the complex and individualized set of considerations that a medical provider might take into account in deciding whether to prescribe an antidepressant like Cymbalta, although it is likely to not be a major factor given the widespread understanding of this risk across similar medications and the primary goal of the physician to treat the depressive or pain condition affecting the patient at the time of the prescription decision.

**REQUEST FOR ADMISSION NO. 7:**

Admit that CYMBALTA's risk of causing adverse symptoms resulting from discontinuation of CYMBALTA is something a reasonable person would consider important in deciding whether to purchase and ingest the medication.

**RESPONSE TO REQUEST FOR ADMISSION NO. 7:**

Subject to Lilly's Objections to Plaintiff's Amended Requests for Admissions, Lilly cannot reasonably respond to this Request given the inherently unique situation presented for every patient, including the severity of their condition and need for treatment, and the fact that every antidepressant contains similar potential risks arising from the discontinuation of antidepressants like Cymbalta, which is stated in Cymbalta's U.S. label, and it is therefore denied.

**REQUEST FOR ADMISSION NO. 8:**

Admit that the gradual or sudden discontinuation of CYMBALTA can cause nausea.

**RESPONSE TO REQUEST FOR ADMISSION NO. 8:**

Subject to Lilly's Objections to Plaintiff's Amended Requests for Admissions, Lilly admits that in some patients who are treated with Cymbalta, the gradual or sudden discontinuation of Cymbalta is associated with nausea, as stated in Cymbalta's U.S. label, although the rate of nausea as observed in the initial short-term clinical trials was low, approximately 5.9 percent as reported in the Perahia article.

**REQUEST FOR ADMISSION NO. 9:**

Admit that the gradual or sudden discontinuation of CYMBALTA can cause headaches.

**RESPONSE TO REQUEST FOR ADMISSION NO. 9:**

Subject to Lilly's Objections to Plaintiff's Amended Requests for Admissions, Lilly admits that in some patients who are treated with Cymbalta, the gradual or sudden discontinuation of Cymbalta is associated with headaches, as stated in Cymbalta's U.S. label, although the rate of headaches as observed in the initial short-term clinical trials was low, approximately 5.3 percent as reported in the Perahia article.

**REQUEST FOR ADMISSION NO. 10:**

Admit that the gradual or sudden discontinuation of CYMBALTA can cause paresthesia.

**RESPONSE TO REQUEST FOR ADMISSION NO. 10:**

Subject to Lilly's Objections to Plaintiff's Amended Requests for Admissions, Lilly admits that in some patients who are treated with Cymbalta, the gradual or sudden discontinuation of Cymbalta is associated paresthesia, as stated in Cymbalta's U.S. label, although the rate of paresthesia as observed in the initial short-term clinical trials was low, approximately 2.9 percent as reported in the Perahia article.

**REQUEST FOR ADMISSION NO. 11:**

Admit that the gradual or sudden discontinuation of CYMBALTA can cause nightmares.

**RESPONSE TO REQUEST FOR ADMISSION NO. 11:**

Subject to Lilly's Objections to Plaintiff's Amended Requests for Admissions, Lilly admits that in some patients who are treated with Cymbalta, the gradual or sudden discontinuation of Cymbalta is associated with nightmares, as stated in Cymbalta's U.S. label that was in use between 2004 and 2010, although the rate of nightmares as observed in the initial short-term clinical trials was low, approximately 2.0 percent as reported in the Perahia article.



**REQUEST FOR ADMISSION NO. 12:**

Admit that the gradual or sudden discontinuation of CYMBALTA can cause insomnia.

**RESPONSE TO REQUEST FOR ADMISSION NO. 12:**

Subject to Lilly's Objections to Plaintiff's Amended Requests for Admissions, Lilly admits that in some patients who are treated with Cymbalta, the gradual or sudden discontinuation of Cymbalta is associated with insomnia, as stated in Cymbalta's U.S. label beginning in 2007, although the rate of insomnia as observed in the initial short-term clinical trials was low, approximately 2.0 percent as reported in the Perahia article.

**REQUEST FOR ADMISSION NO. 13:**

Admit that the gradual or sudden discontinuation of CYMBALTA can cause anxiety.

**RESPONSE TO REQUEST FOR ADMISSION NO. 13:**

Subject to Lilly's Objections to Plaintiff's Amended Requests for Admissions, Lilly admits that in some patients who are treated with Cymbalta, the gradual or sudden discontinuation of Cymbalta is associated with anxiety, as stated in Cymbalta's U.S. label, although the rate of anxiety as observed in the initial short-term clinical trials was low, below 2.0 percent as reported in the Perahia article.

**REQUEST FOR ADMISSION NO. 14:**

Admit that the gradual or sudden discontinuation of CYMBALTA can cause hyperhidrosis.

**RESPONSE TO REQUEST FOR ADMISSION NO. 14:**

Subject to Lilly's Objections to Plaintiff's Amended Requests for Admissions, Lilly admits that in some patients who are treated with Cymbalta, the gradual or sudden discontinuation of Cymbalta is associated with hyperhidrosis, as stated in Cymbalta's U.S. label, although the rate of hyperhidrosis as observed in the initial short-term clinical trials was low, below 2.0 percent as reported in the Perahia article.

**REQUEST FOR ADMISSION NO. 15:**

Admit that the gradual or sudden discontinuation of CYMBALTA can cause sensory disturbances.

**RESPONSE TO REQUEST FOR ADMISSION NO. 15:**

Subject to Lilly's Objections to Plaintiff's Amended Requests for Admissions, Lilly admits that in some patients who are treated with Cymbalta, the gradual or sudden discontinuation of Cymbalta is associated with sensory disturbances, as stated in Cymbalta's U.S. label, although the rate of sensory disturbances as observed in the initial short-term clinical trials was low, below 2.0 percent as reported in the Perahia article.

**REQUEST FOR ADMISSION NO. 16:**

Admit that the gradual or sudden discontinuation of CYMBALTA can cause suicidal ideation.

**RESPONSE TO REQUEST FOR ADMISSION NO. 16:**

Subject to Lilly's Objections to Plaintiff's Amended Requests for Admissions, Lilly responds that it lacks information sufficient to admit this Request, and it is therefore denied. Lilly admits that there had been long-standing concern in the medical community that

antidepressants may have a role in inducing suicidal ideation in certain patients, but a causal relationship has not been established. Studies have not shown an increased risk of suicidal ideation or behaviors in most adult patients treated with Cymbalta compared to those treated with placebo. However, studies show a potential, but not statistically significant, increased risk among young adults (age 18-24). Nevertheless, Cymbalta's U.S. labels warns that "patients being treated with antidepressants should be observed closely for clinical worsening and suicidality, especially at the beginning of a course of drug therapy, or at the time of dose changes, either increases or decreases."

**REQUEST FOR ADMISSION NO. 17:**

Admit that the gradual or sudden discontinuation of CYMBALTA can cause seizures.

**RESPONSE TO REQUEST FOR ADMISSION NO. 17:**

Subject to Lilly's Objections to Plaintiff's Amended Requests for Admissions, Lilly admits that there have been postmarketing reports of cases of seizure or seizure-like symptoms after discontinuation of treatment with Cymbalta and other SSRIs or SNRIs, as warned in sections of Cymbalta's U.S. label quoted in Lilly's Response to Request No. 1 and in Section 6.12 (Postmarketing Spontaneous Reports) added to the label in December 2008, but otherwise denied.

**REQUEST FOR ADMISSION NO. 18:**

Admit that, between 2004 and 2011, LILLY obtained over \$17 billion in revenue from the sale of CYMBALTA within the United States.

**RESPONSE TO REQUEST FOR ADMISSION NO. 18:**

Denied. See <https://investor.lilly.com/annuals.cfm> for information about annual revenue from the sale of Cymbalta in the United States.

**REQUEST FOR ADMISSION NO. 19:**

Admit that CYMBALTA has a shorter half-life than Prozac.

**RESPONSE TO REQUEST FOR ADMISSION NO. 19:**

Admitted.

**REQUEST FOR ADMISSION NO. 20:**

Admit that CYMBALTA has a shorter half-life than Paxil.

**RESPONSE TO REQUEST FOR ADMISSION NO. 20:**

Admitted.

**REQUEST FOR ADMISSION NO. 21:**

Admit that CYMBALTA has a shorter half-life than Zoloft.

**RESPONSE TO REQUEST FOR ADMISSION NO. 21:**

Admitted.

**REQUEST FOR ADMISSION NO. 22:**

Admit that CYMBALTA has a shorter half-life than Celexa.

**RESPONSE TO REQUEST FOR ADMISSION NO. 22:**

Admitted.

**REQUEST FOR ADMISSION NO. 23:**

Admit that CYMBALTA has a shorter half-life than Lexapro.

**RESPONSE TO REQUEST FOR ADMISSION NO. 23:**

Admitted.

**REQUEST FOR ADMISSION NO. 24:**

Admit that Effexor has a shorter half-life than CYMBALTA.

**RESPONSE TO REQUEST FOR ADMISSION NO. 24:**

Admitted.

**REQUEST FOR ADMISSION NO. 25:**

Admit that the shorter the half-life of an SSRI or SNRI, the more frequent the occurrences of WITHDRAWAL.

**RESPONSE TO REQUEST FOR ADMISSION NO. 25:**

Subject to Lilly's Objections to Plaintiff's Amended Requests for Admissions, Lilly admits that there is a relationship between the half-life of an SSRI or SNRI and discontinuation symptoms, in which a shorter half-life is one factor in the likelihood of the appearance of discontinuation-emergent adverse events ("DEAEs"), but that half-life does not explain the entire scientific picture.

**REQUEST FOR ADMISSION NO. 26:**

Admit that Daniel Kajdasz was an employee of LILLY when the PERAHIA ARTICLE was published.

**RESPONSE TO REQUEST FOR ADMISSION NO. 26:**

Admitted.

**REQUEST FOR ADMISSION NO. 27:**

Admit that Durisala Desaiiah was an employee of LILLY when the PERAHIA ARTICLE was published.

**RESPONSE TO REQUEST FOR ADMISSION NO. 27:**

Admitted.

**REQUEST FOR ADMISSION NO. 28:**

Admit that Peter Haddad has received payments from LILLY for attending advisory boards, lecturing, and consultancy work.

**RESPONSE TO REQUEST FOR ADMISSION NO. 28:**

Admitted.

**REQUEST FOR ADMISSION NO. 29:**

Admit that YOU never instructed YOUR sales force to distribute the PERAHIA ARTICLE to physicians when it was published in 2005.

**RESPONSE TO REQUEST FOR ADMISSION NO. 29:**

Lilly is still investigating the nature and extent that the sales force distributed information reflected in the PERAHIA ARTICLE, or the article itself, and thus cannot answer this request at this time.

**REQUEST FOR ADMISSION NO. 30:**

Admit that, in the six acute treatment placebo controlled trials identified in the PERAHIA ARTICLE, 44.3% of patients receiving CYMBALTA reported at least one discontinuation-emergent adverse event.

**RESPONSE TO REQUEST FOR ADMISSION NO. 30:**

Subject to Lilly's Objections to Plaintiff's Amended Requests for Admissions, Lilly admits that in the six acute treatment clinical trials discussed in the PERAHIA ARTICLE, 44.3% of patients receiving Cymbalta reported at least one discontinuation-emergent adverse event following abrupt discontinuation and 22.9% of patients receiving placebo reported at least one discontinuation-emergent adverse event.

**REQUEST FOR ADMISSION NO. 31:**

Admit that, in the six acute treatment placebo controlled trials identified in the PERAHIA ARTICLE, of the 510 discontinuation-emergent adverse events reported, 50.6% were moderate and 9.6% were severe.

**RESPONSE TO REQUEST FOR ADMISSION NO. 31:**

Subject to Lilly's Objections to Plaintiff's Amended Requests for Admissions, Lilly admits that in the six acute treatment clinical trials discussed in the PERAHIA ARTICLE, of the 510 discontinuation-emergent adverse events reported following abrupt discontinuation from Cymbalta, 39.8% were mild, 50.6% were moderate, and 9.6% were characterized as severe.

**REQUEST FOR ADMISSION NO. 32:**

Admit that, in the six acute treatment placebo controlled trials identified in the PERAHIA ARTICLE, 3.1% of patients in the CYMBALTA treatment groups withdrew from the studies because of a discontinuation-emergent adverse event.

**RESPONSE TO REQUEST FOR ADMISSION NO. 32:**

Subject to Lilly's Objections to Plaintiff's Amended Requests for Admissions, Lilly admits that in the six acute treatment clinical trials discussed in the PERAHIA ARTICLE, 3.1% of patients in the Cymbalta treatment groups withdrew from the study due to one or more discontinuation-emergent adverse events following abrupt discontinuation.

**REQUEST FOR ADMISSION NO. 33:**

Admit that, in the six acute treatment placebo controlled trials identified in the PERAHIA ARTICLE, 62.1% of patients taking 120 mg/day of CYMBALTA experienced at least one discontinuation-emergent adverse event.

**RESPONSE TO REQUEST FOR ADMISSION NO. 33:**

Subject to Lilly's Objections to Plaintiff's Amended Requests for Admissions, Lilly admits that in the six acute treatment clinical trials discussed in the PERAHIA ARTICLE, 62.1% of patients receiving 120 mg/day of Cymbalta and 22.9% of patients receiving placebo reported at least one discontinuation-emergent adverse event following abrupt discontinuation.

**REQUEST FOR ADMISSION NO. 34:**

Admit that, in the six acute treatment placebo controlled trials identified in the PERAHIA ARTICLE, of the discontinuation-emergent adverse events reported, 53.7% remained unresolved after two weeks.



**RESPONSE TO REQUEST FOR ADMISSION NO. 34:**

Subject to Lilly's Objections to Plaintiff's Amended Requests for Admissions, Lilly admits that in the six acute treatment clinical trials discussed in the PERAHIA ARTICLE, 53.7% of discontinuation-emergent adverse events reported by patients receiving Cymbalta were unresolved after two weeks and 52.5% of discontinuation-emergent adverse events reported by patients receiving placebo were unresolved after two weeks when the study concluded, but that the patients continued to remain under the care of their medical providers following the study.

**REQUEST FOR ADMISSION NO. 35:**

Admit that, in a fifty-two week open-label clinical trial for CYMBALTA identified in the PERAHIA ARTICLE, 50.8% of patients suffered at least one discontinuation-emergent adverse event.

**RESPONSE TO REQUEST FOR ADMISSION NO. 35:**

Subject to Lilly's Objections to Plaintiff's Amended Requests for Admissions, Lilly admits that in the 52-week open-label clinical trial discussed in the PERAHIA ARTICLE, 50.8% of patients receiving Cymbalta reported at least one discontinuation-emergent adverse event following abrupt discontinuation.

**REQUEST FOR ADMISSION NO. 36:**

Admit that, in a fifty-two week open-label clinical trial for CYMBALTA identified in the PERAHIA ARTICLE, of the discontinuation-emergent adverse events reported, 46.3% were moderate and 17.2% were severe.

**RESPONSE TO REQUEST FOR ADMISSION NO. 36:**

Subject to Lilly's Objections to Plaintiff's Amended Requests for Admissions, Lilly admits that in the 52-week open-label clinical trial discussed in the PERAHIA ARTICLE, of the discontinuation-emergent adverse events reported following abrupt discontinuation, 36.6% were mild, 46.3% were moderate, and 17.2% were characterized as severe.

**REQUEST FOR ADMISSION NO. 37:**

Admit that, in a fifty-two week open-label clinical trial for CYMBALTA identified in the PERAHIA ARTICLE, of the discontinuation-emergent adverse events reported 55.2% had not resolved after two weeks.

**RESPONSE TO REQUEST FOR ADMISSION NO. 37:**

Subject to Lilly's Objections to Plaintiff's Amended Requests for Admissions, Lilly admits that in the 52-week open-label clinical trial discussed in the PERAHIA ARTICLE, of the discontinuation-emergent adverse events reported, 55.2% had not resolved after two weeks when the study concluded, but that the patients continued to remain under the care of their medical providers following the study.

**REQUEST FOR ADMISSION NO. 38:**

Admit that LILLY does not know how long it took for the discontinuation-emergent adverse events discussed in the PERAHIA ARTICLE to fully resolve.

**RESPONSE TO REQUEST FOR ADMISSION NO. 38:**

Denied in part. Lilly admits it knows that of the discontinuation-emergent adverse events reported in the six acute treatment clinical trials discussed in the PERAHIA ARTICLE, 46.3% of those reported by patients receiving Cymbalta and 47.5% of those reported by patients on

placebo resolved within two weeks. Lilly further admits it knows that of the discontinuation-emergent adverse events reported in the two long-term treatment clinical trials discussed in the PERAHIA ARTICLE, 35.3% of those reported by patients receiving Cymbalta resolved within two weeks and 50% of those reported by patients on placebo resolved within one week. Lilly further admits it knows that of the discontinuation-emergent adverse events reported in the 52-week open-label clinical trial discussed in the PERAHIA ARTICLE, 44.8% of those reported resolved within two weeks. Because the trials concluded after the end of two weeks post-discontinuation, the trials did not capture this information from the medical professionals who continued to treat the patients at the conclusion of the trials.

**REQUEST FOR ADMISSION NO. 39:**

Admit that the work conducted in the PERAHIA ARTICLE was funded by LILLY.

**RESPONSE TO REQUEST FOR ADMISSION NO. 39:**

Admitted.

**REQUEST FOR ADMISSION NO. 40:**

Admit that the DEAEs measured in the PERAHIA ARTICLE were assessed by means of spontaneous reports rather than a symptom checklist.

**RESPONSE TO REQUEST FOR ADMISSION NO. 40:**

Subject to Lilly's Objections to Plaintiff's Amended Requests for Admissions, Lilly admits that in the trials discussed in the PERAHIA ARTICLE, DEAEs were assessed by means of an open-ended question posed to patients to solicit information about their adverse symptoms and not by means of a symptom checklist in which patients are asked about each specific symptom.

**REQUEST FOR ADMISSION NO. 41:**

Admit that use of a symptom checklist, instead of spontaneous reports, would be expected to produce higher incidence rates of DEAEs in the PERAHIA ARTICLE.

**RESPONSE TO REQUEST FOR ADMISSION NO. 41:**

Subject to Lilly's Objections to Plaintiff's Amended Requests for Admissions, Lilly admits that the use of a symptom checklist to measure DEAEs might be expected to produce higher reporting rates of DEAEs for both active treatment and placebo than alternate means of assessment in part due to the suggestive influence of a symptom checklist on patients.

**REQUEST FOR ADMISSION NO. 42:**

Admit that LILLY sponsored the clinical trial by Jerrold Rosenbaum et al, Selective Serotonin Reuptake Inhibitor Discontinuation Syndrome: A Randomized Clinical Trial, 44 BIOLOGICAL PSYCHIATRY 2, 77-87 (1998).

**RESPONSE TO REQUEST FOR ADMISSION NO. 42:**

Admitted.

**REQUEST FOR ADMISSION NO. 43:**

Admit that, in Jerrold Rosenbaum et al, Selective Serotonin Reuptake Inhibitor Discontinuation Syndrome: A Randomized Clinical Trial, 44 BIOLOGICAL PSYCHIATRY 2, 77-87 (1998), the researchers used a symptom checklist to tabulate DEAEs / withdrawal symptoms.

**RESPONSE TO REQUEST FOR ADMISSION NO. 43:**

Admitted.

**REQUEST FOR ADMISSION NO. 44:**

Admit that the information contained in the European Medicines Agency Summary of Product Information for CYMBALTA is accurate and true.

**RESPONSE TO REQUEST FOR ADMISSION NO. 44:**

Admitted subject to Lilly's Objections to Plaintiff's Amended Requests for Admissions.

**REQUEST FOR ADMISSION NO. 45:**

Admit that, in clinical trials, adverse events seen on abrupt treatment discontinuation of CYMBALTA occurred in approximately 45% of patients treated with CYMBALTA.

**RESPONSE TO REQUEST FOR ADMISSION NO. 45:**

Denied in part. Lilly admits that in some clinical trials, specifically the six acute treatment clinical trials discussed in the PERAHIA ARTICLE, discontinuation-emergent adverse events after abrupt discontinuation were reported by 44.3% of patients on active treatment and 22.9% on placebo. In other clinical trials, the incidence of DEAEs was a different rate. For example, in the two long-term treatment clinical trials discussed in the PERAHIA ARTICLE, discontinuation-emergent adverse events after abrupt discontinuation were reported by 9.1% of patients.

**REQUEST FOR ADMISSION NO. 46:**

Admit that the following statement appears in the European Medicines Agency Summary of Product Information for CYMBALTA: "In clinical trials adverse events seen on abrupt treatment discontinuation occurred in approximately 45% of patients treated with Cymbalta and 23% of patients taking placebo."

**RESPONSE TO REQUEST FOR ADMISSION NO. 46:**

Admitted.

**REQUEST FOR ADMISSION NO. 47:**

Admit that the following statement does not appear on the CYMBALTA LABEL: “In clinical trials adverse events seen on abrupt treatment discontinuation occurred in approximately 45% of patients treated with Cymbalta and 23% of patients taking placebo.”

**RESPONSE TO REQUEST FOR ADMISSION NO. 47:**

Denied. The above-quoted statement appears in the CYMBALTA LABEL as defined by Plaintiff as “the official prescribing information for the drug, including but not limited to the product insert and medication guides approved by the FDA or other foreign regulatory bodies.”

**REQUEST FOR ADMISSION NO. 48:**

Admit that at no time has LILLY’s direct-to-consumer advertising, i.e., television, newspapers, magazines, and/or radio, warned patients that abrupt discontinuation of CYMBALTA occurred in approximately 45% of patients treated with CYMBALTA.

**RESPONSE TO REQUEST FOR ADMISSION NO. 48:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR ADMISSION NO. 49:**

Admit that the following statement appears in the European Medicines Agency Summary of Product Information for CYMBALTA: “It is therefore advised that duloxetine should be gradually tapered when discontinuing treatment over a period of no less than 2 weeks, according to the patient’s needs (see section 4.2).”

**RESPONSE TO REQUEST FOR ADMISSION NO. 49:**

Admitted.

**REQUEST FOR ADMISSION NO. 50:**

Admit that the CYMBALTA LABEL does not state that CYMBALTA should be gradually tapered “over a period of no less than 2 weeks[.]”

**RESPONSE TO REQUEST FOR ADMISSION NO. 50:**

Denied. The above-quoted statement appears in the CYMBALTA LABEL as defined by Plaintiff as “the official prescribing information for the drug, including but not limited to the product insert and medication guides approved by the FDA or other foreign regulatory bodies.”

**REQUEST FOR ADMISSION NO. 51:**

Admit that the European Medicines Agency Summary of Product Information for CYMBALTA refers to “discontinuation-emergent adverse events” as “withdrawal symptoms.”

**RESPONSE TO REQUEST FOR ADMISSION NO. 51:**

Admitted.

**REQUEST FOR ADMISSION NO. 52:**

Admit that the following statement appears in the European Medicines Agency Summary of Product Information for CYMBALTA: Withdrawal symptoms “may be prolonged (2-3 months or more).”

**RESPONSE TO REQUEST FOR ADMISSION NO. 52:**

Lilly admits that Cymbalta’s European Medicines Agency Summary of Product Characteristics states, concerning discontinuation-emergent adverse events: “Generally these

symptoms are self-limiting and usually resolve within 2 weeks, though in some individuals they may be prolonged (2-3 months or more).”

**REQUEST FOR ADMISSION NO. 53:**

Admit that the CYMBALTA LABEL does not estimate how long discontinuation-emergent adverse events will likely take to resolve following abrupt or tapered discontinuation of CYMBALTA.

**RESPONSE TO REQUEST FOR ADMISSION NO. 53:**

Denied. An estimate of the duration of discontinuation-emergent adverse events appears in the CYMBALTA LABEL as defined by Plaintiff as “the official prescribing information for the drug, including but not limited to the product insert and medication guides approved by the FDA or other foreign regulatory bodies.”

**REQUEST FOR ADMISSION NO. 54:**

Admit that the CYMBALTA LABEL does not indicate that some individuals may have withdrawal symptoms for 2-3 months or more.

**RESPONSE TO REQUEST FOR ADMISSION NO. 54:**

Denied. A statement that some individuals may experience prolonged discontinuation-emergent adverse events for 2-3 months or more appears in the CYMBALTA LABEL as defined by Plaintiff as “the official prescribing information for the drug, including but not limited to the product insert and medication guides approved by the FDA or other foreign regulatory bodies.”



**REQUEST FOR ADMISSION NO. 55:**

Admit that the CYMBALTA LABEL does not specify what percentage of patients will likely experience at least one discontinuation-emergent adverse event upon abrupt or tapered discontinuation of CYMBALTA.

**RESPONSE TO REQUEST FOR ADMISSION NO. 55:**

Denied. A statement of the percentage of patients who reported discontinuation-emergent adverse events in clinical trials appears in the CYMBALTA LABEL as defined by Plaintiff as “the official prescribing information for the drug, including but not limited to the product insert and medication guides approved by the FDA or other foreign regulatory bodies.”

**REQUEST FOR ADMISSION NO. 56:**

Admit that YOU, not the FDA, bear responsibility for the content of the CYMBALTA LABEL at all times.

**RESPONSE TO REQUEST FOR ADMISSION NO. 56:**

Lilly refers Plaintiff to its objections to this Request.

**REQUEST FOR ADMISSION NO. 57:**

Admit that the smallest approved dose for CYMBALTA is 20 mg.

**RESPONSE TO REQUEST FOR ADMISSION NO. 57:**

Admitted.

**REQUEST FOR ADMISSION NO. 58:**

Admit that CYMBALTA has an elimination half-life of about 12 hours (range 8 to 17 hours).

**RESPONSE TO REQUEST FOR ADMISSION NO. 58:**

Admitted.

**REQUEST FOR ADMISSION NO. 59:**

Admit that CYMBALTA should be swallowed whole and should not be chewed or crushed.

**RESPONSE TO REQUEST FOR ADMISSION NO. 59:**

Admitted.

**REQUEST FOR ADMISSION NO. 60:**

Admit that the CYMBALTA capsule should not be opened and its contents sprinkled on food or mixed with liquids.

**RESPONSE TO REQUEST FOR ADMISSION NO. 60:**

Admitted.

**REQUEST FOR ADMISSION NO. 61:**

Admit that opening a CYMBALTA capsule, or crushing or chewing the CYMBALTA capsule, might affect its enteric coating.

**RESPONSE TO REQUEST FOR ADMISSION NO. 61:**

Admitted.

Respectfully Submitted,

Dated: March 9, 2015

By: \_\_\_\_\_/s/  
Jeffrey T. Bozman (83679)  
Covington & Burling LLP  
One CityCenter  
850 Tenth Street, NW  
Washington, DC 20001  
Tel: (202) 662-5829  
Fax: (202) 778-5829  
*Counsel for Eli Lilly and Company*

**CERTIFICATE OF SERVICE**

I, Jeffrey T. Bozman, hereby certify that on the 9th day of March, 2015, I have served Plaintiff's counsel in this action with a copy of Defendant's Responses to Plaintiff's First Set of Requests for Admission by mailing a copy of the same by United States Mail, postage prepaid, and electronic mail to the following address:

Peter A. Miller  
**Miller Legal LLC**  
175 S. Pantops Drive, Third Floor  
Charlottesville, VA 2291  
Telephone (434) 529-6909  
Facsimile (888) 830-1488  
PMiller@MillerLegalLLC.com  
*Counsel for Gilda Hagan-Brown*

Dated: March 9, 2015

By:                     /s/                      
Jeffrey T. Bozman (83679)  
Covington & Burling LLP  
One CityCenter  
850 Tenth Street, NW  
Washington, DC 20001  
Tel: (202) 662-5829  
Fax: (202) 778-5829  
*Counsel for Eli Lilly and Company*

## Exhibit 6-A

**UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF VIRGINIA  
ALEXANDRIA DIVISION**

GILDA HAGAN-BROWN

Plaintiff,

v.

ELI LILLY AND COMPANY, an Indiana  
corporation,

Defendant.

CASE NO.: 1:14-CV-01614-AJT-JFA

**PLAINTIFF’S FIRST SET OF INTERROGATORIES TO DEFENDANT**

**PROPOUNDING PARTY:** Plaintiff, Gilda Hagan-Brown

**RESPONDING PARTY:** Defendant Eli Lilly and Company

**SET NO.:** ONE

Plaintiff Gilda Hagan-Brown (“PLAINTIFF”), by and through her attorneys, and pursuant to Federal Rule of Civil Procedure 26 and 33, hereby serve written requests upon Defendant Eli Lilly and Company, (“LILLY”) to answer the following interrogatories in writing, under oath, and in accordance with the following definitions and instructions, within thirty (30) days of service.

**DEFINITIONS**

The following definitions apply to each request below and are incorporated therein:

1. “ALL” means “any and all” and the word “any” means “any and all.”
2. The term “CYMBALTA” means duloxetine hydrochloride, including any other name or trademark under which it is sold, domestically *or* abroad, marketed or produced, including products sold, marketed, or produced by others if they do so with your permission, at

your request, at your direction, with your acquiescence, and/or if you gain any benefit from their sales, marketing, or distribution.

3. The term “COMMUNICATION” means and refers to every method and manner of transmitting or receiving data, opinions, thoughts, inquiries, representations and other information, whether orally, in writing, electronically, or otherwise, between two or more persons or entities. Communications include drafts and other written information intended for communicating to another person, even if not ultimately transmitted to or received by another person.

4. The term “IDENTIFY” (in reference to a person) means to state, to the extent known, the person’s full name, present or last known address, telephone number, company title (to the extent applicable), and whether or not the person is currently an employee of LILLY (to the extent applicable).

5. The terms “CONCERNING,” “RELATING,” and/or “REGARDING” mean containing, alluding to, responding to, commenting upon, discussing, explaining, mentioning, analyzing, constituting, memorializing, comprising, repeating, incorporating, confirming, listing, evidencing, setting forth, summarizing, or characterizing, either directly or indirectly, in whole or in part.

6. The term “DEAE” means Discontinuation Emergent Adverse Event, and refers to any possible side effects or symptoms relating to discontinuing, withdrawing, or tapering from the use, consumption, or treatment with Cymbalta.

7. The term “WITHDRAWAL” includes discontinuation or tapering, as well as DEAEs, withdrawal symptoms, and any side effects of withdrawing, discontinuing, or tapering from CYMBALTA.

8. The term “DOCUMENT” shall have the broadest meaning possible under Rule 34 of the Federal Rules of Civil Procedure and includes all originals and drafts, in any and all languages, of any nature whatsoever, in your possession, custody or control, regardless of where located, and include, but are not limited to, letters, correspondence, logs, drafts, contracts, prospective contracts, agreements, reports, records, studies, surveys, resolutions, tabulations, notes, summaries, memoranda, Electronically Stored Information (“ESI”), electronic mail (“email”), calendar or diary entries, handwritten notes, working papers, work sheets, spread sheets, diagrams, minutes of meetings, agendas, bulletins, periodicals, circulars, advertisements, notices, announcements, invoices, statements, checks (front and back), bank statements, ledgers, orders, vouchers, instructions, drawings, charts, graphs, manuals, brochures, pamphlets, schedules, telegrams, teletypes, photographs, audio tapes, voice-mail messages, videotapes, electronic recordings, facsimile transmissions, and information of whatever kind either stored on computers, including computer disks, hard drives and other media, or contained in any computer or information retrieval devices.

9. The terms “ELI LILLY,” “LILLY,” “YOU” or “YOUR” refer to Eli LILLY and Company, its respective officers, directors, employees, representatives, subsidiaries, and affiliates thereof, as well as all persons acting for, on behalf of, or in concert with Eli LILLY and Company’s behalf, including agents, attorneys, accountants, and investigators.

10. The term “FDA” means the United States Food & Drug Administration.

11. The term “INCLUDING” means “including, but not limited to.”

12. The term “LABEL” refers to the official prescribing information for the drug, including but not limited to the product insert and medication guides approved by the FDA or other foreign regulatory bodies.



13. The term “MEDICAL PROFESSIONAL” includes healthcare providers, prescribing doctors, non-prescribing doctors, physicians, pharmacists, nurses, and other individuals who provide healthcare services.

14. The term “PERAHIA ARTICLE” refers to David G. Perahia, *et al.*, *Symptoms Following Abrupt Discontinuation of Duloxetine Treatment in Patients with Major Depressive Disorder*, 89 J. Affective Disorders 207-12 (2005).

15. The term “SNRI” means serotonin norepinephrine reuptake inhibitor.

16. The term “SSRI” means selective serotonin reuptake inhibitor.

17. The use of the terms “or,” “and,” and “and/or” should be construed conjunctively and disjunctively for the broadest possible meaning.

18. The term “person” or “people” includes individuals, corporations, partnerships, associations, and other bodies and entities, as well as their representatives, agents, employees and attorneys.

19. The terms “research,” “study,” or “analysis,” when used as a noun mean and refer to any research, analysis, study, report, evaluation or assessment. The term research when used as a verb means to research, analyze, study, report, evaluate, or assess.

20. The term “use” means to “employ something for a purpose,” “to do something habitually,” “to consume something,” “to manipulate,” “to benefit from,” as well as to allow others to “use,” or acquiesce in others’ “use.”

21. The singular use of any term or phrase includes its plural, and the plural of any term or phrase includes its singular.

22. The use of any tense of any verb shall also include within its meaning all other tenses of that verb.

## **INTERROGATORIES**

### **INTERROGATORY NO. 1:**

Please IDENTIFY all current and former employees or consultants who were involved in drafting, editing, creating, and submitting to the FDA, the sections of the US CYMBALTA LABEL titled “Discontinuation of Treatment with Cymbalta,” and/or “Dosage and Administration” or “Medication Administration” or “Information for Patients” (depending on year).

### **INTERROGATORY NO. 2:**

Please IDENTIFY all LILLY current and former employees who worked on CYMBALTA in the following department/divisions/sections of LILLY:

- Global Scientific Communications and Information
- Regulatory Affairs
- The LILLY Answer Center
- US Brand Cymbalta Team
- Global Labeling Department
- Discovery and Early phase teams
- Global Medical Affairs
- Global Patient Safety
- Global/Product Development
- Neuroscience Strategy Group
- Any CYMBALTA-specific committee, team, or group

### **INTERROGATORY NO. 3:**

For each category below, please IDENTIFY ten (10) current or former employees or consultants who are knowledgeable, at least in part, on the following topics. If an individual only has knowledge of a subpart of one of these topics, please explain:

- The marketing and advertising of CYMBALTA to MEDICAL PROFESSIONALS
- The marketing and advertising of CYMBALTA to consumers
- The drafting, editing, creating, and submitting to the FDA of the US CYMBALTA LABEL, with specific reference to the sections of the label titled “Discontinuation of Treatment with Cymbalta,” “Dosage and Administration” or “Medication Administration” or “Information for Patients” (depending on year).
- The drafting, editing, creating, and submitting to the European Medicines Agency of

the CYMBALTA LABEL, with specific reference to the sections of the label concerning WITHDRAWAL.

- CYMBALTA WITHDRAWAL
- Clinical trials related to CYMBALTA and WITHDRAWAL
- Domestic regulatory issues related to CYMBALTA
- Foreign regulatory issues related to CYMBALTA
- Educational programs for CYMBALTA
- Training of sales representatives relative to CYMBALTA

**INTERROGATORY NO. 4:**

Please IDENTIFY all non-employee medical doctors retained, paid, or compensated in any way (directly or indirectly), by or on behalf of LILLY to present materials and information about CYMBALTA to other doctors, including but not limited to Key Opinion Leaders (KOLs), Thought Leaders and doctors on LILLY's Speaker's Bureau.

**INTERROGATORY NO. 5:**

Please list, by year, the total amount of payments, including but not limited to any compensation, gifts, payments, honoraria, or consulting fees, made to those individuals identified in Interrogatory No. 4.

**INTERROGATORY NO. 6:**

Please IDENTIFY all third-party vendors used by LILLY to organize, create, and/or conduct for education programs wherein CYMBALTA was discussed.

**INTERROGATORY NO. 7:**

Please IDENTIFY all third-parties that LILLY consulted with and/or hired to engage in direct-to-consumer advertising for CYMBALTA.

**INTERROGATORY NO. 8:**

Please IDENTIFY all third-parties that LILLY consulted with and/or hired to plan and/or publish medical journal articles related to CYMBALTA.

**INTERROGATORY NO. 9:**

Please IDENTIFY all third-parties that LILLY consulted with and/or hired to engage in public relations related to CYMBALTA.

**INTERROGATORY NO. 10:**

Please IDENTIFY all sales representatives employed by LILLY or by a third-party contracted by LILLY to provide information to MEDICAL PROFESSIONALS healthcare providers concerning CYMBALTA who visited the following:

- Dr. Mohammed Bahadori (prescriber)  
Arthritis Care Center, P.C.  
14904 Jefferson Davis Hwy, Suite 203  
Woodbridge, VA 22192  
(703) 492-6660

**INTERROGATORY NO. 11:**

Please list, by year, the total amount of payments, including but not limited to any compensation, gifts, payments, honoraria, or consulting fees, made to:

- Dr. Mohammed Bahadori (prescriber)  
Arthritis Care Center, P.C.  
14904 Jefferson Davis Hwy, Suite 203  
Woodbridge, VA 22192  
(703) 492-6660

**INTERROGATORY NO. 12:**

Please list the title, date, duration, and location of any LILLY-sponsored education program that discussed CYMBALTA, attended by any of the following, divided by individual:

- Dr. Mohammed Bahadori (prescriber)  
Arthritis Care Center, P.C.  
14904 Jefferson Davis Hwy, Suite 203  
Woodbridge, VA 22192  
(703) 492-6660

**INTERROGATORY NO. 13:**

Please explain, to the best of LILLY's knowledge, why adverse reactions sometimes occur upon the discontinuation of CYMBALTA treatment.

**INTERROGATORY NO. 14:**

Please explain LILLY's reason for changing the US LABEL concerning "Discontinuation of Treatment with Cymbalta" in 2008 from "the following symptoms occurred at a rate greater than or equal to 2%" to "the following symptoms occurred at a rate greater than or equal to 1%."

**INTERROGATORY NO. 15:**

Please explain LILLY's reason for adding to the 2009 US CYMBALTA LABEL "or tapered" in the context of "Following abrupt ... discontinuation ..." in the section titled "Discontinuation of Treatment with Cymbalta."

**INTERROGATORY NO. 16:**

Please explain LILLY's reason for changing the US CYMBALTA LABEL in 2012 from "the following symptoms occurred at a rate greater than or equal to 1%" to "at 1% or greater" in the section titled "Discontinuation of Treatment with Cymbalta."

**INTERROGATORY NO. 17:**

Please explain the reason LILLY included in its labeling in European countries that adverse events seen on abrupt treatment discontinuation of CYMBALTA occurred in approximately 45% of patients treated with CYMBALTA, but did not disclose that information on the FDA-approved LABEL.

**INTERROGATORY NO. 18:**

Provide the citation of every journal publication that LILLY sponsored, paid for, or was

otherwise involved in creating, that relates to WITHDRAWAL associated with SSRIs or SNRIs, including but not limited to CYMBALTA, Prozac, Zoloft, Paxil, and Effexor.

**INTERROGATORY NO. 19:**

Provide the citation of every journal publication that LILLY sponsored, paid for, or was otherwise involved in creating, that relates to CYMBALTA.

**INTERROGATORY NO. 20:**

Provide the citation of every journal publication that LILLY sponsored, paid for, or was otherwise involved in creating, that relates to the down regulation of neurotransmitters and any SSRI or SNRI, including but not limited to CYMBALTA, Prozac, Zoloft, Paxil, and Effexor.

**INTERROGATORY NO. 21:**

List every placebo-controlled, active-controlled, and open-label clinical trial involving CYMBALTA, which contained a measurement designed to measure WITHDRAWAL, indicating for each trial: the date of the trial (started and completed); the location of the trial; whether the trial was completed as part of an Investigational New Drug Application, and if so, its designation; whether the trial was published in a medical journal, and if so, the citation; and whether the results of the trial were shared with the FDA.

**INTERROGATORY NO. 22:**

Please state the amount of revenue, by year, that LILLY obtained from the sale of CYMBALTA within the United States between its approval in 2004 and the present.

Dated: February 4, 2015

Respectfully submitted,

**MILLER LEGAL, LLC**

/s/ Brielle M. Hunt  
\_\_\_\_\_  
Brielle M. Hunt  
Miller Legal, LLC  
175 South Pantops Drive, Ste. 301  
Charlottesville, Virginia 22911

Tel: (434) 529-6909  
Fax: (800) 768-9542  
Email: [bhunt@millerlegalllc.com](mailto:bhunt@millerlegalllc.com)

-and-

**BAUM HEDLUND ARISTEI & GOLDMAN,  
P.C.**

/s/ R. Brent Wisner  
Brent Wisner, Esq. (*pro hac vice*)  
12100 Wilshire Blvd., Suite 950  
Los Angeles, CA 90025  
(310) 207-3233  
(310) 207-4204 (fax)  
Email: [rbwisner@baumgedlundlaw.com](mailto:rbwisner@baumgedlundlaw.com)

**CERTIFICATE OF SERVICE**

I hereby certify that on this 4<sup>th</sup> day of February, 2015, a true and correct copy of the foregoing **PLAINTIFF'S FIRST SET OF INTERROGATORIES TO DEFENDANT** was served via Electronic Mail, upon the following:

Jeffrey Todd Bozman  
Brett C. Reynolds (pro hac vice)  
Michael X. Imbroscio (pro hac vice)  
Phyllis A. Jones (pro hac vice)  
**COVINGTON & BURLING LLP**  
One City Center  
850 Tenth Street, NW  
Washington, DC 20001  
Email: [jbozman@cov.com](mailto:jbozman@cov.com)  
Email: [breynolds@cov.com](mailto:breynolds@cov.com)  
Email: [mimbrosio@cov.com](mailto:mimbrosio@cov.com)  
Email: [pajones@cov.com](mailto:pajones@cov.com)

*Attorneys for Eli Lilly and Company*

/s/

\_\_\_\_\_  
Samantha Jison



## Exhibit 6-B

**UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF VIRGINIA  
ALEXANDRIA DIVISION**

GILDA HAGAN-BROWN

Plaintiff,

v.

ELI LILLY AND COMPANY, an Indiana  
corporation,

Defendant.

CASE NO.: 1:14-CV-01614-AJT-JFA

**DEFENDANT’S OBJECTIONS TO PLAINTIFF’S FIRST SET OF  
INTERROGATORIES**

Defendant Eli Lilly and Company (“Defendant” or “Lilly”) hereby submits its objections to Plaintiff’s First Set of Interrogatories, as follows:

**GENERAL STATEMENTS AND OBJECTIONS**

Lilly objects to these Interrogatories as exceeding Federal Rule of Civil Procedure 33’s limitation on the number of interrogatories that may be propounded by a party without leave of court. Lilly construes these Interrogatories as totaling forty-one (41), including all subparts. Subject to this objection, Lilly has addressed all the following interrogatories.

**OBJECTIONS TO DEFINITIONS**

1. Lilly objects to the definitions of the terms “ELI LILLY”, “LILLY”, “YOU”, and “YOUR” to the extent that they seek to extend these definitions to persons or entities other than the named Defendant in this litigation, Eli Lilly and Company, and purport to call for information or documents that are not in the possession, custody, or control of Eli Lilly and Company. For purposes of its objections and responses, Lilly will define “ELI LILLY”,

“LILLY”, “YOU”, and “YOUR” to mean Eli Lilly and Company. Lilly will limit its responses to information and documents that are in the possession, custody, or control of Eli Lilly and Company.

2. Lilly objects to the definition of “DOCUMENT” to the extent that it imposes obligations on Lilly beyond those in the Federal Rules of Civil Procedure.

### **SPECIFIC OBJECTIONS TO INTERROGATORIES**

#### **INTERROGATORY NO. 1:**

Please IDENTIFY all current and former employees or consultants who were involved in drafting, editing, creating, and submitting to the FDA, the sections of the US CYMBALTA LABEL titled “Discontinuation of Treatment with Cymbalta,” and/or “Dosage and Administration” or “Medication Administration” or “Information for Patients” (depending on year).

#### **OBJECTIONS TO INTERROGATORY NO. 1:**

Lilly objects to this Interrogatory as overly broad and unduly burdensome as to time and scope and to the use of “involved” as vague and ambiguous. Scores of Lilly employees have had some involvement in Cymbalta’s labeling over the last 10 years, and the voluminous documents that have already been provided to Plaintiff’s counsel, including the regulatory files for Cymbalta, contain extensive information about the Lilly employees and other individuals who have worked on labeling issues. Requiring Lilly to compile a list of “all” such individuals is not reasonable, especially since the identity of such individuals is now also in Plaintiff’s possession. When it responds to this Interrogatory, Lilly will make a good faith effort to identify the key employees or consultants who played a significant role in or were responsible for the creation of Cymbalta’s United States Package Insert (“U.S. label”).

**INTERROGATORY NO. 2:**

Please IDENTIFY all LILLY current and former employees who worked on CYMBALTA in the following department/divisions/sections of LILLY:

- Global Scientific Communications and Information
- Regulatory Affairs
- The LILLY Answer Center
- US Brand Cymbalta Team
- Global Labeling Department
- Discovery and Early phase teams
- Global Medical Affairs
- Global Patient Safety
- Global/Product Development
- Neuroscience Strategy Group
- Any CYMBALTA-specific committee, team, or group

**OBJECTIONS TO INTERROGATORY NO. 2:**

This Interrogatory essentially seeks a listing of every employee who has ever had any role in Cymbalta, which likely subsumes hundreds if not thousands of Lilly employees.

Compiling such a comprehensive list would be nearly impossible, and the burden of attempting to do so far outweighs any conceivable need for such information. Lilly is willing to discuss identifying certain key employees with central relevant responsibilities for Cymbalta, but Lilly cannot respond to this request as written, and therefore objects to the Interrogatory in its entirety. (Lilly also notes that this Interrogatory as written contains eleven (11) discrete subparts, each concerning a different department, division, or team within Lilly. As such, Lilly construes this as eleven separate interrogatories.)

**INTERROGATORY NO. 3:**

For each category below, please IDENTIFY ten (10) current or former employees or consultants who are knowledgeable, at least in part, on the following topics. If an individual only has knowledge of a subpart of one of these topics, please explain:

- The marketing and advertising of CYMBALTA to MEDICAL PROFESSIONALS
- The marketing and advertising of CYMBALTA to consumers
- The drafting, editing, creating, and submitting to the FDA of the US CYMBALTA LABEL, with specific reference to the sections of the label titled “Discontinuation of Treatment with Cymbalta,” Dosage and Administration” or “Medication Administration” or “Information for Patients” (depending on year).
- The drafting, editing, creating, and submitting to the European Medicines Agency of the CYMBALTA LABEL, with specific reference to the sections of the label concerning WITHDRAWAL.
- CYMBALTA WITHDRAWAL
- Clinical trials related to CYMBALTA and WITHDRAWAL
- Domestic regulatory issues related to CYMBALTA
- Foreign regulatory issues related to CYMBALTA
- Educational programs for CYMBALTA
- Training of sales representatives relative to CYMBALTA

**OBJECTIONS TO INTERROGATORY NO. 3:**

This Interrogatory seeks a listing of 100 employees who had a broad range of roles relating to Cymbalta. Compiling such a comprehensive list would be nearly impossible, and the burden of attempting to do so far outweighs any conceivable need for information of this scope. Lilly is willing to discuss identifying certain key employees with central relevant responsibilities for Cymbalta, but Lilly cannot respond to this request as written, and therefore objects to the Interrogatory in its entirety. (Lilly also notes that this Interrogatory as written contains eleven (10) discrete subparts, each concerning a different department, division, or team within Lilly. As such, Lilly construes this as ten separate interrogatories.)

**INTERROGATORY NO. 4:**

Please IDENTIFY all non-employee medical doctors retained, paid, or compensated in any way (directly or indirectly), by or on behalf of LILLY to present materials and information about CYMBALTA to other doctors, including but not limited to Key Opinion Leaders (KOLs), Thought Leaders and doctors on LILLY's Speaker's Bureau.

**OBJECTIONS TO INTERROGATORY NO. 4:**

Lilly objects to this Interrogatory as overly broad as to time and scope. Lilly also objects to the this Interrogatory to the extent it mischaracterizes the role of Key Opinion Leaders, Thought Leaders, or any other Lilly-affiliated non-employee doctors. Lilly will be responding to this Interrogatory with information about external payments to physicians by reference to the extensive information on this subject already provided to Plaintiff's counsel.

**INTERROGATORY NO. 5:**

Please list, by year, the total amount of payments, including but not limited to any compensation, gifts, payments, honoraria, or consulting fees, made to those individuals identified in Interrogatory No. 4.

**OBJECTIONS TO INTERROGATORY NO. 5:**

Lilly objects to this Interrogatory as overly broad as to time and scope. As noted above, Lilly will be responding to this Interrogatory with information about external payments to physicians by reference to the extensive information on this subject already provided to Plaintiff's counsel.

**INTERROGATORY NO. 6:**

Please IDENTIFY all third-party vendors used by LILLY to organize, create, and/or conduct for education programs wherein CYMBALTA was discussed.

**OBJECTIONS TO INTERROGATORY NO. 6:**

Lilly objects to this Interrogatory as overly broad and unduly burdensome as to time and scope. To the extent that this Interrogatory seeks identification of “all third-parties,” the burden of complying with this Interrogatory outweighs Plaintiff’s need for information of this scope. As such, Lilly will identify the principal agencies retained for education programs to the extent those programs contained Cymbalta-specific information.

**INTERROGATORY NO. 7:**

Please IDENTIFY all third-parties that LILLY consulted with and/or hired to engage in direct-to-consumer advertising for CYMBALTA.

**OBJECTIONS TO INTERROGATORY NO. 7:**

Lilly objects to this Interrogatory as overly broad and unduly burdensome as to time and scope. To the extent that this Interrogatory seeks identification of “all third-parties,” the burden of complying with this Interrogatory outweighs Plaintiff’s need for information of this scope. As such, Lilly will identify the principal agencies retained for Cymbalta direct-to-consumer advertising.

**INTERROGATORY NO. 8:**

Please IDENTIFY all third-parties that LILLY consulted with and/or hired to plan and/or publish medical journal articles related to CYMBALTA.

**OBJECTIONS TO INTERROGATORY NO. 8:**

Lilly objects to this Interrogatory to the extent it implies that Lilly pays medical journals or third parties to publish Lilly-sponsored articles. Lilly also objects to this Interrogatory as overly broad as to time and scope to the extent that it seeks Lilly to identify every individual who had any involvement in the publication of any article relating to Cymbalta. Plaintiff is aware of the publications involving Cymbalta that relate to the discontinuation symptoms that are the focus of this lawsuit, the authors and associated disclosures appear on the face of those articles, and Plaintiffs have already deposed a principal author of those articles in *Hexum v. Eli Lilly & Co.*, Case No. 2:12-cv-2701-SVW (MAN) (C.D. Cal) and *Herrera v. Eli Lilly & Co.*, Case No. 2:12-cv-2702-SVW (MAN) (C.D. Cal.) (“the *Hexum/Herrera* actions”). Lilly will not be responding to this Interrogatory.

**INTERROGATORY NO. 9:**

Please IDENTIFY all third-parties that LILLY consulted with and/or hired to engage in public relations related to CYMBALTA.

**OBJECTIONS TO INTERROGATORY NO. 9:**

Lilly objects to this Interrogatory as overly broad as to time and scope. Lilly’s engagement of public relations agencies is not relevant to this matter nor likely to lead to the discovery of admissible evidence, and Lilly will not be responding to this Interrogatory.

**INTERROGATORY NO. 10:**

Please IDENTIFY all sales representatives employed by LILLY or by a third-party contracted by LILLY to provide information to MEDICAL PROFESSIONALS healthcare providers concerning CYMBALTA who visited the following:



- Dr. Mohammed Bahadori (prescriber) Arthritis Care Center, P.C.  
14904 Jefferson Davis Hwy, Suite 203  
Woodbridge, VA 22192  
(703) 492-6660

**OBJECTIONS TO INTERROGATORY NO. 10:**

Lilly objects to this Interrogatory to the extent it seeks information from third parties not in Lilly's possession. Otherwise, Lilly has no objection.

**INTERROGATORY NO. 11:**

Please list, by year, the total amount of payments, including but not limited to any compensation, gifts, payments, honoraria, or consulting fees, made to:

- Dr. Mohammed Bahadori (prescriber) Arthritis Care Center, P.C.  
14904 Jefferson Davis Hwy, Suite 203  
Woodbridge, VA 22192  
(703) 492-6660

**OBJECTIONS TO INTERROGATORY NO. 11:**

Lilly has no objection.

**INTERROGATORY NO. 12:**

Please list the title, date, duration, and location of any LILLY-sponsored education program that discussed CYMBALTA, attended by any of the following, divided by individual:

- Dr. Mohammed Bahadori (prescriber) Arthritis Care Center, P.C.  
14904 Jefferson Davis Hwy, Suite 203  
Woodbridge, VA 22192  
(703) 492-6660

**OBJECTIONS TO INTERROGATORY NO. 12:**

Lilly has no objection.

**INTERROGATORY NO. 13:**

Please explain, to the best of LILLY's knowledge, why adverse reactions sometimes occur upon the discontinuation of CYMBALTA treatment.

**OBJECTIONS TO INTERROGATORY NO. 13:**

Lilly objects to this Interrogatory to the extent it poses a complex medical question that does not lend itself to an answer in this format. Lilly will be responding by reference to documents, scientific articles, and prior testimony concerning this subject.

**INTERROGATORY NO. 14:**

Please explain LILLY's reason for changing the US LABEL concerning "Discontinuation of Treatment with Cymbalta" in 2008 from "the following symptoms occurred at a rate greater than or equal to 2%" to "the following symptoms occurred at a rate greater than or equal to 1%."

**OBJECTIONS TO INTERROGATORY NO. 14:**

Lilly has no objection.

**INTERROGATORY NO. 15:**

Please explain LILLY's reason for adding to the 2009 US CYMBALTA LABEL "or tapered" in the context of "Following abrupt ... discontinuation ..." in the section titled "Discontinuation of Treatment with Cymbalta."

**OBJECTIONS TO INTERROGATORY NO. 15:**

Lilly has no objection.

**INTERROGATORY NO. 16:**

Please explain LILLY's reason for changing the US CYMBALTA LABEL in 2012 from "the following symptoms occurred at a rate greater than or equal to 1%" to "at 1% or greater" in the section titled "Discontinuation of Treatment with Cymbalta."

**OBJECTIONS TO INTERROGATORY NO. 16:**

Lilly has no objection.

**INTERROGATORY NO. 17:**

Please explain the reason LILLY included in its labeling in European countries that adverse events seen on abrupt treatment discontinuation of CYMBALTA occurred in approximately 45% of patients treated with CYMBALTA, but did not disclose that information on the FDA-approved LABEL.

**OBJECTIONS TO INTERROGATORY NO. 17:**

Lilly objects to this Interrogatory to the extent that it is argumentative and mischaracterizes Lilly's actions or motives in the creation of its U.S. label for Cymbalta. Lilly will respond substantively to this Interrogatory as to the origin of the language in the European label ("SmPC").

**INTERROGATORY NO. 18:**

Provide the citation of every journal publication that LILLY sponsored, paid for, or was otherwise involved in creating, that relates to WITHDRAWAL associated with SSRIs or SNRIs, including but not limited to CYMBALTA, Prozac, Zoloft, Paxil, and Effexor.

**OBJECTIONS TO INTERROGATORY NO. 18:**

Lilly objects to this Interrogatory as overly broad and unduly burdensome as to time and scope and to the extent it is not limited to journal articles concerning Cymbalta. The Complaint does not allege that Plaintiff was treated with Prozac, Zoloft, Paxil, or Effexor, and as such, those medicines are irrelevant to this matter. Lilly also objects to this Interrogatory as Lilly-sponsored journal publications are available in the public domain, Lilly authors' involvement with those articles is reflected in a disclosure statement in each article, and Plaintiff can find the information it seeks through this Interrogatory through an online literature search. Lilly will not be compiling a list of journal articles for Plaintiff.

**INTERROGATORY NO. 19:**

Provide the citation of every journal publication that LILLY sponsored, paid for, or was otherwise involved in creating, that relates to CYMBALTA.

**OBJECTIONS TO INTERROGATORY NO. 19:**

Lilly objects to this Interrogatory as overly broad and unduly burdensome as to time and scope. Plaintiff already has the citations for the three principal articles reporting on Lilly-sponsored trials involving Cymbalta that address discontinuation-emergent adverse events, which are fully available in the public domain, Lilly authors' involvement with those articles is reflected in a disclosure statement in each article, and Plaintiff can find the information it seeks through this Interrogatory through an online literature search. Lilly will not be compiling a list of all journal articles relating to Cymbalta for Plaintiff.

**INTERROGATORY NO. 20:**

Provide the citation of every journal publication that LILLY sponsored, paid for, or was otherwise involved in creating, that relates to the down regulation of neurotransmitters and any SSRI or SNRI, including but not limited to CYMBALTA, Prozac, Zoloft, Paxil, and Effexor.

**OBJECTIONS TO INTERROGATORY NO. 20:**

See objections to Interrogatories Nos. 18 and 19. Lilly will not be compiling a list of journal articles for Plaintiff.

**INTERROGATORY NO. 21:**

List every placebo-controlled, active-controlled, and open-label clinical trial involving CYMBALTA, which contained a measurement designed to measure WITHDRAWAL, indicating for each trial: the date of the trial (started and completed); the location of the trial; whether the trial was completed as part of an Investigational New Drug Application, and if so, its designation; whether the trial was published in a medical journal, and if so, the citation; and whether the results of the trial were shared with the FDA.

**OBJECTIONS TO INTERROGATORY NO. 21:**

Lilly objects to this Interrogatory as unduly burdensome as it assigns Lilly the burden of compiling and sorting voluminous amounts of clinical trial information. Plaintiff has access to Lilly's Investigational New Drug application and New Drug Application productions in the *Hexum/Herrera* actions, which include Cymbalta clinical trials, protocols, labeling, and regulatory correspondence located through a reasonably diligent search. Lilly will make a good faith effort to identify Cymbalta clinical trials relating to each New Drug Application and the

corresponding Bates numbers in Lilly's existing voluminous production so Plaintiff can identify the specific information it seeks through this Interrogatory.

**INTERROGATORY NO. 22:**

Please state the amount of revenue, by year, that LILLY obtained from the sale of CYMBALTA within the United States between its approval in 2004 and the present.

**OBJECTIONS TO INTERROGATORY NO. 22:**

Lilly has no objection. Lilly will be responding to this Interrogatory by reference to publicly available information.

Respectfully Submitted,

Dated: February 23, 2015

By: \_\_\_\_\_/s/  
Jeffrey T. Bozman (83679)  
Covington & Burling LLP  
One CityCenter  
850 Tenth Street, NW  
Washington, DC 20001  
Tel: (202) 662-5829  
Fax: (202) 778-5829  
*Counsel for Eli Lilly and Company*

**CERTIFICATE OF SERVICE**

I, Jeffrey T. Bozman, hereby certify that on the 23rd day of February, 2015, I have served Plaintiff's counsel in this action with a copy of Defendant's Objections to Plaintiff's First Set of Interrogatories by mailing a copy of the same by United States Mail, postage prepaid, and electronic mail to the following address:

Peter A. Miller  
**Miller Legal LLC**  
175 S. Pantops Drive, Third Floor  
Charlottesville, VA 2291  
Telephone (434) 529-6909  
Facsimile (888) 830-1488  
PMiller@MillerLegalLLC.com  
*Counsel for Gilda Hagan-Brown*

Dated: February 23, 2015

By:                     /s/                      
Jeffrey T. Bozman (83679)  
Covington & Burling LLP  
One CityCenter  
850 Tenth Street, NW  
Washington, DC 20001  
Tel: (202) 662-5829  
Fax: (202) 778-5829  
*Counsel for Eli Lilly and Company*

## Exhibit 6-C



**UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF VIRGINIA  
ALEXANDRIA DIVISION**

GILDA HAGAN-BROWN

Plaintiff,

v.

ELI LILLY AND COMPANY, an Indiana  
corporation,

Defendant.

CASE NO.: 1:14-CV-01614

**DEFENDANT’S RESPONSE TO PLAINTIFF’S FIRST SET OF INTERROGATORIES**

Defendant Eli Lilly and Company (“Defendant” or “Lilly”) hereby submits its responses to Plaintiff’s First Set of Interrogatories, as follows:

**GENERAL STATEMENT**

The following responses are subject to Lilly’s Objections to Plaintiff’s First Set of Interrogatories served on February 23, 2015 pursuant to Federal Rule of Civil Procedure 33 and Local Civil Rule 26 and, for the sake of brevity, not repeated herein. Lilly has not fully completed its investigation of the facts relating to this case, its discovery, or its preparation for trial. Both discovery and independent investigation are ongoing. Therefore, all responses contained herein are based solely upon such information and documents as are both presently available and specifically known to Lilly. Lilly reserves the right to supplement these responses as discovery and this investigation proceed. Lilly’s responses are in accordance with the requirements of the Federal Rules of Civil Procedure, the Local Rules, and any applicable Court Orders.

**RESPONSES TO INTERROGATORIES**

**INTERROGATORY NO. 1:**

Please IDENTIFY all current and former employees or consultants who were involved in drafting, editing, creating, and submitting to the FDA, the sections of the US CYMBALTA LABEL titled “Discontinuation of Treatment with Cymbalta,” and/or “Dosage and Administration” or “Medication Administration” or “Information for Patients” (depending on year).

**RESPONSE TO INTERROGATORY NO. 1:**

Subject to and without waiving its Objections to Plaintiff’s First Set of Interrogatories, Lilly responds that the key employees or consultants who played a significant role in or were responsible for the creation and updates of Cymbalta’s United States Physicians Package Insert (“U.S. label”) were Nayan Acharya, Mark Bangs, Bryan Boggs, Greg Brophy, Sharon Hoog, Anne Sakai-Robbins, Antonio Crucitti, Madeleine Wohlreich, and Matt Kuntz, Isabelle Murray.

**INTERROGATORY NO. 2:**

Please IDENTIFY all LILLY current and former employees who worked on CYMBALTA in the following department/divisions/sections of LILLY:

- Global Scientific Communications and Information
- Regulatory Affairs
- The LILLY Answer Center
- US Brand Cymbalta Team
- Global Labeling Department
- Discovery and Early phase teams
- Global Medical Affairs
- Global Patient Safety
- Global/Product Development
- Neuroscience Strategy Group
- Any CYMBALTA-specific committee, team, or group

**RESPONSE TO INTERROGATORY NO. 2:**

Lilly refers Plaintiff to its objections to this Interrogatory.

**INTERROGATORY NO. 3:**

For each category below, please IDENTIFY ten (10) current or former employees or consultants who are knowledgeable, at least in part, on the following topics. If an individual only has knowledge of a subpart of one of these topics, please explain:

- The marketing and advertising of CYMBALTA to MEDICAL PROFESSIONALS
- The marketing and advertising of CYMBALTA to consumers
- The drafting, editing, creating, and submitting to the FDA of the US CYMBALTA LABEL, with specific reference to the sections of the label titled “Discontinuation of Treatment with Cymbalta,” Dosage and Administration” or “Medication Administration” or “Information for Patients” (depending on year).
- The drafting, editing, creating, and submitting to the European Medicines Agency of the CYMBALTA LABEL, with specific reference to the sections of the label concerning WITHDRAWAL.
- CYMBALTA WITHDRAWAL
- Clinical trials related to CYMBALTA and WITHDRAWAL
- Domestic regulatory issues related to CYMBALTA
- Foreign regulatory issues related to CYMBALTA
- Educational programs for CYMBALTA
- Training of sales representatives relative to CYMBALTA

**RESPONSE TO INTERROGATORY NO. 3:**

Lilly refers Plaintiff to its objections to this Interrogatory.

**INTERROGATORY NO. 4:**

Please IDENTIFY all non-employee medical doctors retained, paid, or compensated in any way (directly or indirectly), by or on behalf of LILLY to present materials and information about CYMBALTA to other doctors, including but not limited to Key Opinion Leaders (KOLs), Thought Leaders and doctors on LILLY’s Speaker’s Bureau.

**RESPONSE TO INTERROGATORY NO. 4:**

Subject to and without waiving its Objections to Plaintiff's First Set of Interrogatories, Lilly responds that information about non-employee doctors associated with Lilly in relation to Cymbalta can be found in Faculty Reports, Contract Status Reports, and Activity Detail Reports within its existing production at CYM-02739356 - CYM-02777355.

**INTERROGATORY NO. 5:**

Please list, by year, the total amount of payments, including but not limited to any compensation, gifts, payments, honoraria, or consulting fees, made to those individuals identified in Interrogatory No. 4.

**RESPONSE TO INTERROGATORY NO. 5:**

Subject to and without waiving its Objections to Plaintiff's First Set of Interrogatories, Lilly refers Plaintiff to its response to Interrogatory No. 4

**INTERROGATORY NO. 6:**

Please IDENTIFY all third-party vendors used by LILLY to organize, create, and/or conduct for education programs wherein CYMBALTA was discussed.

**RESPONSE TO INTERROGATORY NO. 6:**

Subject to and without waiving its Objections to Plaintiff's First Set of Interrogatories, Lilly responds that Lilly-sponsored education programs are not branded with Cymbalta-specific content.

**INTERROGATORY NO. 7:**

Please IDENTIFY all third-parties that LILLY consulted with and/or hired to engage in direct-to-consumer advertising for CYMBALTA.

**RESPONSE TO INTERROGATORY NO. 7:**

Subject to and without waiving its Objections to Plaintiff's First Set of Interrogatories, Lilly responds that it used the advertising agency DraftFCB for direct-to-consumer advertising of Cymbalta from 2004 through 2013. Thereafter, the entity changed its name to FCB.

**INTERROGATORY NO. 8:**

Please IDENTIFY all third-parties that LILLY consulted with and/or hired to plan and/or publish medical journal articles related to CYMBALTA.

**RESPONSE TO INTERROGATORY NO. 8:**

Lilly refers Plaintiff to its objections to this Interrogatory.

**INTERROGATORY NO. 9:**

Please IDENTIFY all third-parties that LILLY consulted with and/or hired to engage in public relations related to CYMBALTA.

**RESPONSE TO INTERROGATORY NO. 9:**

Lilly refers Plaintiff to its objections to this Interrogatory.

**INTERROGATORY NO. 10:**

Please IDENTIFY all sales representatives employed by LILLY or by a third-party contracted by LILLY to provide information to MEDICAL PROFESSIONALS healthcare providers concerning CYMBALTA who visited the following:

- Dr. Mohammed Bahadori (prescriber) Arthritis Care Center, P.C.  
14904 Jefferson Davis Hwy, Suite 203  
Woodbridge, VA 22192  
(703) 492-6660

**RESPONSE TO INTERROGATORY NO. 10:**

Subject to and without waiving its Objections to Plaintiff's First Set of Interrogatories, Lilly responds that the following sales representatives visited Dr. Bahadori in relation to Cymbalta: Michael Christov-Bakargiev, Michelle Daniels, Kellie Eldridge, Anneliesa Hundt, Lindsey Hurt, Emily Huyler, Kristen Kollhoff, Greyson McGrail, Theresa Murphy, Maria Pote, Mohammed Sajanalal, Cem Sakarya, and sales representatives from third-party NQ Neuro.

**INTERROGATORY NO. 11:**

Please list, by year, the total amount of payments, including but not limited to any compensation, gifts, payments, honoraria, or consulting fees, made to:

- Dr. Mohammed Bahadori (prescriber) Arthritis Care Center, P.C.  
14904 Jefferson Davis Hwy, Suite 203  
Woodbridge, VA 22192  
(703) 492-6660

**RESPONSE TO INTERROGATORY NO. 11:**

Lilly responds that no compensation has been paid by Lilly to Dr. Bahadori.

**INTERROGATORY NO. 12:**

Please list the title, date, duration, and location of any LILLY-sponsored education program that discussed CYMBALTA, attended by any of the following, divided by individual:

- Dr. Mohammed Bahadori (prescriber) Arthritis Care Center, P.C.  
14904 Jefferson Davis Hwy, Suite 203  
Woodbridge, VA 22192  
(703) 492-6660

**RESPONSE TO INTERROGATORY NO. 12:**

Lilly responds that it has no record of attendance by Dr. Bahadori at any Lilly-sponsored education program.

**INTERROGATORY NO. 13:**

Please explain, to the best of LILLY's knowledge, why adverse reactions sometimes occur upon the discontinuation of CYMBALTA treatment.

**RESPONSE TO INTERROGATORY NO. 13:**

Subject to and without waiving its Objections to Plaintiff's First Set of Interrogatories, Lilly responds that several biochemical mechanisms have been proposed to account for symptoms that can appear following discontinuation of antidepressant treatment. For discussion of some of these theories, Lilly refers Plaintiff to the expert report of Doug Jacobs served in the *Hexum/Herrera* actions at page 21; Lilly's Cymbalta medical information letters on discontinuation symptoms (*see, e.g.*, CYM-0172876 - CYM-01727884); and the following articles:

- Zajecka J, Tracy KA, and Mitchell S (1997), Discontinuation Symptoms After Treatment With Serotonin Reuptake Inhibitors: A Literature Review, *J. Clin. Psychiatry*, 58(7); 291-297.
- Blier P and Tremblay P (2006), Physiologic mechanisms underlying the antidepressant discontinuation syndrome, *J. Clin. Psychiatry*, 67(4): 8-13.
- Schatzberg AF, Blier P, Delgado PL, Fava M, Haddad PM and Shelton RC (2006), Antidepressant Discontinuation Syndrome: Consensus Panel Recommendations for Clinical Management and Additional Research, *J. Clin. Psychiatry*, 67(supp. 4):27-30.

**INTERROGATORY NO. 14:**

Please explain LILLY's reason for changing the US LABEL concerning "Discontinuation of Treatment with Cymbalta" in 2008 from "the following symptoms occurred

at a rate greater than or equal to 2%” to “the following symptoms occurred at a rate greater than or equal to 1%.”

**RESPONSE TO INTERROGATORY NO. 14:**

Lilly responds that in 2007 it changed the frequency cutoff in the U.S. label’s section “Discontinuation of Treatment with Cymbalta” from 2% to 1% based on a review of its clinical trial database for all Cymbalta indications approved by FDA at the time. This review identified five additional discontinuation-emergent adverse events (“DEAEs”) that would be reported using a 1% frequency cutoff. Therefore the 1% cutoff was adopted in order to include those additional DEAEs in the label. In addition, a 1% cutoff was more consistent with the existing categories of adverse event reporting frequencies as set forth by the Council for International Organizations of Medical Sciences (“CIOMS”). *See* CYM-01111108 - CYM-01111178; CYM-01112815 - CYM-01112850; Deposition of Christine Phillips, July 18, 2014 at 207:14-209:24.

**INTERROGATORY NO. 15:**

Please explain LILLY’s reason for adding to the 2009 US CYMBALTA LABEL “or tapered” in the context of “Following abrupt ... discontinuation ...” in the section titled “Discontinuation of Treatment with Cymbalta.”

**RESPONSE TO INTERROGATORY NO. 15:**

Lilly responds that in 2007 it added “or tapered” to the U.S. label’s section “Discontinuation of Treatment with Cymbalta” based on a review of its clinical trial database of all Cymbalta indications approved by FDA at the time. Lilly felt that by this time, it had conducted an adequate number of studies measuring discontinuation-emergent adverse events in the context of tapered discontinuation (rather than only abrupt discontinuation) to warrant this



addition to the label. *See* CYM-01113160 - CYM-01113267; Deposition of Christine Phillips, July 18, 2014 at 210:1-16.

**INTERROGATORY NO. 16:**

Please explain LILLY's reason for changing the US CYMBALTA LABEL in 2012 from "the following symptoms occurred at a rate greater than or equal to 1%" to "at 1% or greater" in the section titled "Discontinuation of Treatment with Cymbalta."

**RESPONSE TO INTERROGATORY NO. 16:**

Lilly responds that in 2010 it changed the phrase "at a rate greater than or equal to 1%" to "at 1% or greater" in the U.S. label's section "Discontinuation of Treatment with Cymbalta" simply for grammatical reasons to shorten and improve clarity.

**INTERROGATORY NO. 17:**

Please explain the reason LILLY included in its labeling in European countries that adverse events seen on abrupt treatment discontinuation of CYMBALTA occurred in approximately 45% of patients treated with CYMBALTA, but did not disclose that information on the FDA-approved LABEL.

**RESPONSE TO INTERROGATORY NO. 17:**

Subject to and without waiving Lilly's Objections to Plaintiff's First Set of Interrogatories, Lilly responds that the European regulatory body required Lilly and all other manufacturers of antidepressants to update the respective Summary of Product Characteristics ("SPC") for such medicines with "core SPC language" that was similar across all SSRIs and SNRIs. This class labeling language included a statement of the percentage of patients in clinical trials who had adverse events on discontinuation of Cymbalta and the percentage of

patients taking placebo who experienced adverse events. *See* CYM-01865850 - CYM-01865854.

Although FDA had the exact same data as the European regulatory authorities, FDA did not make a parallel request or requirement for similar information in Cymbalta's U.S. label. Instead, FDA required that all U.S. labels for SSRIs and SNRIs include a two-paragraph statement about discontinuation symptoms that had been reported during the marketing of medicines in the class and instructions to taper patients off the medicine when stopping treatment.

**INTERROGATORY NO. 18:**

Provide the citation of every journal publication that LILLY sponsored, paid for, or was otherwise involved in creating, that relates to WITHDRAWAL associated with SSRIs or SNRIs, including but not limited to CYMBALTA, Prozac, Zoloft, Paxil, and Effexor.

**RESPONSE TO INTERROGATORY NO. 18:**

Lilly refers Plaintiff to its objections to this Interrogatory.

**INTERROGATORY NO. 19:**

Provide the citation of every journal publication that LILLY sponsored, paid for, or was otherwise involved in creating, that relates to CYMBALTA.

**RESPONSE TO INTERROGATORY NO. 19:**

Lilly refers Plaintiff to its objections to this Interrogatory.

**INTERROGATORY NO. 20:**

Provide the citation of every journal publication that LILLY sponsored, paid for, or was otherwise involved in creating, that relates to the down regulation of neurotransmitters and any SSRI or SNRI, including but not limited to CYMBALTA, Prozac, Zoloft, Paxil, and Effexor.

**RESPONSE TO INTERROGATORY NO. 20:**

Lilly refers Plaintiff to its objections to this Interrogatory and its objections to Interrogatories Nos. 18 and 19.

**INTERROGATORY NO. 21:**

List every placebo-controlled, active-controlled, and open-label clinical trial involving CYMBALTA, which contained a measurement designed to measure WITHDRAWAL, indicating for each trial: the date of the trial (started and completed); the location of the trial; whether the trial was completed as part of an Investigational New Drug Application, and if so, its designation; whether the trial was published in a medical journal, and if so, the citation; and whether the results of the trial were shared with the FDA.

**RESPONSE TO INTERROGATORY NO. 21:**

Subject to and without waiving its Objections to Plaintiff's First Set of Interrogatories, Lilly refers Plaintiff to Attachment A, which identifies the Bates numbers corresponding to Cymbalta clinical trials located through a reasonably diligent search of Lilly's existing production. They are organized generally according to the New Drug Application to which they relate and include, among others, clinical trials that measured discontinuation-emergent adverse events.

**INTERROGATORY NO. 22:**

Please state the amount of revenue, by year, that LILLY obtained from the sale of CYMBALTA within the United States between its approval in 2004 and the present.

**RESPONSE TO INTERROGATORY NO. 22:**

Lilly responds that its annual revenue from sales of Cymbalta in the United States is published in its annual financial reports, available at <https://investor.lilly.com/annuals.cfm>

Respectfully Submitted,

Dated: March 9, 2015

By: \_\_\_\_\_/s/  
Jeffrey T. Bozman (83679)  
Covington & Burling LLP  
One CityCenter  
850 Tenth Street, NW  
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Tel: (202) 662-5829  
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*Counsel for Eli Lilly and Company*

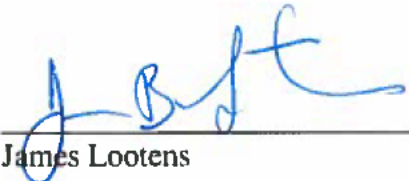
VERIFICATION

Re: *Hagan-Brown v. Eli Lilly & Company*

I, James Lootens , am Assistant Secretary of Eli Lilly and Company and am authorized to provide Verification of discovery responses. Some of the information and facts within the responses is not within my personal knowledge. Such information has been assembled by authorized employees and/or counsel of Lilly who have informed me that the information and facts are true and accurate. Therefore, I verify the foregoing Defendant's Responses to Plaintiff's First Set of Interrogatories as true and accurate.

I declare under penalty of perjury that the foregoing is true and accurate.

Executed on this 9 day of March, 2015.

  
James Lootens

UNITED STATES OF AMERICA

STATE OF INDIANA )

) SS

COUNTY OF MARION )

Before me, a Notary Public for Johnson County, State of Indiana, personally appeared  
James Lootens and acknowledged the execution of the foregoing instrument  
this 9 day of March, 2015.

Heather Richards



NOTARY PUBLIC

Printed Name: Heather Richards

My Commission Expires: 4-29-16

Resident of: Johnson County

(SEAL)

**CERTIFICATE OF SERVICE**

I, Jeffrey T. Bozman, hereby certify that on the 9th day of March, 2015, I have served Plaintiff's counsel in this action with a copy of Defendant's Responses to Plaintiff's First Set of Interrogatories by mailing a copy of the same by United States Mail, postage prepaid, and electronic mail to the following address:

Peter A. Miller  
**Miller Legal LLC**  
175 S. Pantops Drive, Third Floor  
Charlottesville, VA 2291  
Telephone (434) 529-6909  
Facsimile (888) 830-1488  
PMiller@MillerLegalLLC.com  
*Counsel for Gilda Hagan-Brown*

Dated: March 9, 2015

By:                     /s/                      
Jeffrey T. Bozman (83679)  
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*Counsel for Eli Lilly and Company*

## Exhibit 7



**BAUM HEDLUND ARISTEI GOLDMAN** <sup>PC</sup>  
— CONSUMER ATTORNEYS —

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March 13, 2015

Jeffery T. Bozman  
Covington & Burling LLP  
One City Center  
850 Tenth Street, N.W.  
Washington, D.C. 20001

Re: *Hagan-Brown v. Eli Lilly and Company*, 14-CV-1614 (E.D. Va.)  
*Ali v. Eli Lilly and Company*, 14-CV-1615 (E.D. Va.)  
**Discovery Deficiencies – Requests for Production**

Dear Mr. Bozman,

This letter is in response to Defendant Eli Lilly and Company's ("Lilly") responses to Plaintiffs Janine Ali's and Gilda Hagan-Brown's First Set of Requests for Production ("RFPs"), which were served on Plaintiffs by e-mail on March 9, 2015. The RFPs were originally served on Lilly by e-mail on February 4, 2015.

As a general comment, Lilly did not produce a single document in response to these 105 requests for production. This is an egregious abuse of the discovery process and Plaintiffs would ask that Lilly take swift action to rectify this. Lilly is fully aware that we are under an incredibly tight timeline, and blanket refusals to provide responses to document requests that are clearly relevant only undermines the ability of the parties to complete discovery by the cut-off date. Many depositions will need to take place and almost none of those can occur until Lilly makes a complete document production. I implore you to take this letter seriously, as Plaintiffs will file a comprehensive motion to compel on any and all of these requests absent a complete and reasonably diligent supplemental production within six days. There is simply no time to waste.

I have systematically gone through every response and objection levied by Lilly to these RFPs and I have identified those RFPs that are deficient and require immediate attention.

I recommend you take a moment to read through this letter and review Lilly's responses and objections. Then, I think we should sit down for a lengthy meet and confer early next week to systematically go over each paragraph contained herein. It will be a long meeting, but I am willing to take as many hours as needed to either come to a compromise or determine that we are at an impasse that warrants a motion. I am available anytime Tuesday or Wednesday to have this discussion. Please let me know what time works for you.

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**RFP No. 1**

This request asks Lilly to produce all of Lilly's Electronic Common Technical Document ("eCTD") submissions to the FDA for all Cymbalta indications. Instead of producing these eCTDs, however, Lilly directs Plaintiffs to various non-electronic, non-native documents from its previous production in prior litigation. This is not what Plaintiffs requested nor is it in compliance with the request. Plaintiffs want the actual eCTDs that Lilly has submitted, not scanned print outs of those documents (or bits and pieces of those submissions), which are almost entirely useless. We have obtained eCTDs in their native format in previous litigation with other pharmaceutical companies, and there is no reason for Lilly's failure to produce them here in their native format, viewable in an html browser. Please produce all eCTDs submitted to the FDA concerning Cymbalta within six days of this letter or Plaintiffs will file an appropriate motion with the Court.

**RFP No. 2**

This request asks Lilly to produce the Summary Basis of Approval for Cymbalta for each indication. Instead of producing *any* responsive documents, Lilly objects, arguing that the request is (1) too broad and unduly burdensome, (2) *might* have already been produced in prior litigation, and (3) seeks publicly available information because the SBA is created by the FDA. Respectfully, these objections are without merit. First, producing the summary basis of approval for a drug's various indications is commonplace in pharmaceutical litigation. Lilly has each SBA readily on-hand and should be able to produce these without any burden. *See, e.g.*, CYM-01510972 (FDA requesting copy of SBA from Lilly). Second, based on our review of the documents produced so far—a review that has been impeded by excessive redactions and inaccurate OCR data—there are no SBAs in the previous production. Third, the only SBA available for Cymbalta on Drug@FDA is the initial approval of Cymbalta for depression. There are no other SBAs available. *See* [http://www.accessdata.fda.gov/drugsatfda\\_docs/nda/2004/021427\\_s000\\_Cymbalta.cfm](http://www.accessdata.fda.gov/drugsatfda_docs/nda/2004/021427_s000_Cymbalta.cfm). Thus, Plaintiffs require that Lilly comply with this request and produce all SBAs within six days of this letter or Plaintiffs will file an appropriate motion with the Court.

**RFP Nos. 8 and 9**

These requests ask Lilly to produce the transcripts of, and submissions to, any FDA Advisory Committee Meeting related to Cymbalta. Lilly refuses to produce any documents "to the extent" these requests involve "publicly available information." There is no legal authority supporting this ground for refusing to produce documents. If Lilly is in possession of these documents, then they must be produced pursuant to Fed. R. Civ. P. 34. If Lilly does not have these documents, then Lilly must state so. As it stands, this discovery response is deficient. Unless Lilly produces these documents or certifies that it does not possess them within six days of this letter, Plaintiffs will file an appropriate motion with the Court.

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**RFP No. 13**

This request asks Lilly to produce all documents “related to any COMMUNICATIONS with the FDA about CYMBALTA” containing one of the following search terms:

DEAE, withdrawal, discontinuation or discontinuing, dependence, habit-forming, addiction, quitting, tapering, brain zaps, electric shock, down regulation, half-life, missed dose, “greater than or equal to,” Perahia, Rosenbaum, or Schatzberg

Lilly, however, refuses to produce *any* documents responding to this request. Instead, Lilly states that its prior production of documents included “email files from nine Lilly employees who had significant involvement in or responsibility for Cymbalta” and that it has produced some communications “between Lilly and the FDA about Cymbalta and discontinuation-emergent adverse events[.]” As you know, it is our position that Lilly’s prior production is woefully deficient. Lilly’s prior productions consist of approximately 100,000 documents, none of which are in their native format, there are many duplicates and a many documents are thousands of pages long (2500 to 10,000 pages long), the documents are redacted without explanation, and there are many placeholders that state “withheld for privilege,” yet Lilly has failed to produce a privilege log for these withheld documents. Lilly’s prior document productions do not capture what this request is seeking. Plaintiffs are not looking for Lilly’s cherry-picked communications produced in a different case. Plaintiffs want *every* communication between *any* Lilly employee and *any* person at the FDA that contain the words and phrases listed above. This request is reasonably calculated to lead to discoverable information and is clearly relevant to this lawsuit. Please produce responsive documents within six days of this letter, or Plaintiffs will file an appropriate motion with the Court.

**RFP No. 14**

This request seeks production of documents “related to any COMMUNICATIONS with the FDA about Prozac or fluoxetine containing” a discrete list of search terms (same as above for RFA No. 13). Lilly responds by directing Plaintiffs to a prior production of documents related to Prozac. Please certify that the documents identified in Lilly’s response were produced using the above search terms and, thus, comprise the entirety of responsive documents. If not, please properly respond to this request within six days of this letter, or Plaintiffs will file an appropriate motion with the Court.

**RFP Nos. 16, 17, 19, and 20**

These requests ask Lilly to produce all communications Lilly has had with the FDA about two sections in the Cymbalta label and about specific issues related to Cymbalta and withdrawal. Instead of providing any substantive response, Lilly directs Plaintiffs to its response to RFA No. 1. And, Lilly’s response to RFP No. 1 is, as discussed above, non-responsive. It appears Lilly is simply trying to direct Plaintiffs to *all* the regulatory documents that Lilly previously produced,

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but that is not what this request seeks. It seeks all communications between Lilly and the FDA about specific sections of the label. If Lilly believes it has responded to this request in previous productions, please specify the responsive bates numbers. As Plaintiffs stated in the instructions provided with the RFAs:

In response to each request, please specifically reference which Bates numbered pages are responsive to *that* request. Generalized reference to categories of documents is the equivalent of no response at all.

If Lilly has not previously produced responsive documents to *this* request, please produce those responsive documents within six days of this letter, or Plaintiffs will file an appropriate motion with the Court.

**RFP Nos. 22, 48, 80, and 83**

Please advise when Plaintiffs can expect the promised productions. Time is of the essence in these cases and Plaintiffs need these documents as soon as possible.

**RFP No. 23**

This request asks Lilly to produce its “electronic Adverse Event Reporting database for CYMBALTA.” Instead of producing this database, however, Lilly directs to various documents in prior productions that relate to adverse event reporting related to Cymbalta. In addition, Lilly directs Plaintiffs to documents reflecting “postmarketing adverse event data from the Lilly Safety System for serious, unlisted events coded with at least one” of five terms. Although this response is technically not responsive, Plaintiffs will accept it for now, provided Lilly discloses a list of all event codes used in Lilly’s Safety System. This will allow Plaintiffs to see if there are any other adverse events reports that might capture various withdrawal events beyond the five chosen by Lilly. Please provide these event codes within six days of this letter, or Plaintiffs will file an appropriate motion with the Court.

**RFP Nos. 24, 25, 26, and 36**

These requests seek production of all “internal COMMUNICATIONS and/or deliberations concerning” three sections of the Cymbalta label that are at the heart of this litigation and the preparation of “letters used by LILLY to respond to inquiries regarding CYMBALTA” withdrawal. These communications include “all emails, memorandums, drafts, comments, edits, redlines, or discussions about those edits” of specific sections of the Cymbalta label. Lilly, however, refuses to produce any documents responsive to these requests. Instead, Lilly directs Plaintiffs to a prior document production which included emails from nine cherry-picked Lilly employees. This does not even come close to being responsive. Limiting a search to nine employees, when there are likely hundreds of people who played significant roles in the development of Cymbalta is nothing but an attempt to hide relevant discovery. Indeed, limiting

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discovery to *nine* people when Lilly boasts that it employees 39,000 employees worldwide is absurd. See Key Facts, Lilly at a Glance, <http://www.lilly.com/about/key-facts/Pages/key-facts.aspx>.

Simply put, these requests are calculated to lead to relevant information and Lilly's categorical refusal to produce these documents is unsupported. First, Lilly claims that the terms "deliberations" and "discussions" are vague and ambiguous. Not true. Plaintiffs specify the types of documents that are the focus of the requests, eliminating any possible ambiguity or vagueness. Next, Lilly claims that conducting a company-wide search for responsive documents would be too burdensome and "outweighs Plaintiffs' need for documents of this scope." This argument is also without merit. Running searches for responsive documents on a company-wide email system is hardly burdensome and is, quite frankly, routine in pharmaceutical litigation. The fact that Lilly did not produce a single document even though it is fully aware of the accelerated nature of this proceeding, speaks of bad faith.

Obtaining internal Lilly communications about the development and creation of the very sections of a label that are at issue in this lawsuit and letters used to communicate the withdrawal risk to physicians and patients is *the most important discovery* in this case. As it stands, Lilly's response is nonresponsive. Please produce responsive documents within six days of this letter, or Plaintiffs will file an appropriate motion with the Court.

#### **RFP Nos. 27 and 28**

These requests seek production of all documents reflecting Lilly's reason for changing the language in Cymbalta withdrawal warning in 2008 and 2009. Lilly does not provide any responsive documents but, instead, directs Plaintiffs to its responses to Interrogatory Nos. 14 and 15. This is not appropriate. These are requests for *production*, not interrogatories, and nothing in the rules allows a defendant to respond to a request for production by responding to an interrogatory. As it stands, Lilly's response is deficient. Please supplement immediately with responsive documents within six days of this letter, or Plaintiffs will file an appropriate motion with the Court.

#### **RFP No. 29**

This request seeks production of documents that reflect Lilly's "reason for changing the CYMBALTA LABEL in 2012 from 'the following symptoms occurred at a rate greater than or equal to 1%' to 'at 1% or greater' in the section titled 'Discontinuation of Treatment with Cymbalta.'" Lilly does not provide any responsive documents. Instead, Lilly levies the identical boilerplate objections that it has for other relevant requests, i.e., RFPs 24-26. This is inappropriate. Lilly has not offered a valid reason why it would not produce documents responsive to this narrowly tailored request and, thus, is in violation of the rules. Please supplement immediately with responsive documents within six days of this letter, or Plaintiffs will file an appropriate motion with the Court.

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**RFP Nos. 30, 31, 32, and 33**

These requests seek production of documents related to the design of the Cymbalta capsule, which Plaintiffs allege is defective. To all of these requests, Lilly refuses to produce *any* documents and, instead, issues the following objection:

Lilly objects to this Request as overly broad and unduly burdensome as to time and scope and to the extent it seeks documents previously produced by Lilly in productions to which Plaintiff has access. Lilly also objects to this Request to the extent that it seeks document concerning Cymbalta's design or manufacture that are not limited to documents about any alleged discontinuation-emergent adverse events potentially arising from Cymbalta treatment and therefore seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence.

These objections are largely incomprehensible and without merit. First, the "overly burdensome" objection is nothing but boilerplate malarkey and is unfounded. There is nothing particularly burdensome about producing documents related to Lilly's design of the Cymbalta capsule. Second, Lilly's claim that prior discovery productions contained responsive documents is false. In the prior cases, there were no design defect claims. Thus, there was no discovery about the design of the Cymbalta capsule. Third, Lilly's argument that it does not have to produce documents related to a design defect claim because it is not relevant makes no sense. Plaintiffs allege that Cymbalta's capsule design was defective, which made it impossible to safely taper off the drug. Discovery about this issue is, by definition, relevant. Refusing to produce documents about a relevant issue is inappropriate.

Lilly's refusal to produce *any* responsive documents about Plaintiffs' design defect claims is in violation of the Rules. Please supplement immediately with responsive documents within six days of this letter, or Plaintiffs will file an appropriate motion with the Court.

**RFP No. 35**

This request asks Lilly to run targeted searches of the email accounts of people identified by Lilly that were involved with the development of specific sections of the Cymbalta label (Interrogatory No. 1) and who Lilly believes has knowledge of specific topics (Interrogatory No. 3). Lilly did identify ten individuals in response to Interrogatory No. 1 (although, it appears that Lilly's response is incomplete as discussed in a separate letter related to Lilly's deficiencies in responding to Plaintiffs' interrogatories), but did not provide any documents associated with those individuals in response to this request. Lilly refused to identify any individuals in responding to Interrogatory No. 3, so there could be no documents produced related to those individuals.



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Putting aside Lilly's failure to properly respond to Interrogatory Nos. 1 and 3, Lilly's response to RFP No. 35 is also deficient. Lilly simply makes boilerplate objections about the burden being overwhelming—a fact that could not possibly be true since Lilly has never actually established how many people would be identified in Interrogatory Nos. 1 and 3. Moreover, Lilly objects to the use of the search terms “anti!”, “addict!”, and “habit!”, “greater than or equal to”, or “delayed release” as overly broad. Respectfully, this is neither accurate nor fair. The request contains *search stings* that have two terms in each search. For example, if an email has “anti!” in it, then it must also have one of the following terms in it as well: DEAE!, discon!, withd!, taper!, cold w/1turkey, addict!, habit!, paresth!, zap!, electric w/4 shock, dizz!, Rosenbaum, Schatzberg, Glenmullen, half-life, “missed dose,” downregu!, “greater than or equal to,” Perahia, enteric, pellets, “delayed release.” If an email has a “anti!” and, for example, “discon!” in it, then there is high probability it will be an email discussing the discontinuation of an antidepressant. While this search might also yield some additional non-relevant documents, this targeted search is reasonably calculated to lead to admissible evidence and, thus, is discoverable. Lilly's blanket refusal to run any searches is inappropriate, especially since Plaintiffs gave Lilly the exact searches that they needed to obtain discoverable information. As it stands, Lilly's response is deficient. Please supplement immediately with responsive documents within six days of this letter, or Plaintiffs will file an appropriate motion with the Court.

**RFP No. 38**

This request asks Lilly to produce “all minutes of any LILLY committee, working group, department, board, etc. where CYMBALTA and WITHDRAWAL were discussed.” Lilly refuses to produce any responsive documents. Lilly directs Plaintiffs to a set of boilerplate objections that, on their face, cannot be valid. Obtaining minutes of meetings within Lilly where the very topic that is the subject of this lawsuit was discussed is clearly relevant to this lawsuit. Moreover, there is no reason why obtaining these meeting minutes would be unduly burdensome. Asking a pharmaceutical company to produce meeting minutes concerning topics that are at the heart of this litigation is a *basic* discovery request. Lilly has not produced any meeting minutes related to this topic and, evidently, has made no effort to obtain and produce these highly relevant and discoverable documents. As such, Lilly's response is deficient and its objections are groundless. Please supplement with responsive documents within six days of this letter, or Plaintiffs will file an appropriate motion with the Court.

**RFP Nos. 39 and 41**

These requests seek production of internal communications relating to “why the rate of WITHDRAWAL reflected in the PERAHIA article was not included in the US LABEL” and communications relating to Effexor withdrawal—the primary competitor to Cymbalta. Lilly, once again, did not produce any responsive documents and instead directs Plaintiffs' to boilerplate objections about how producing these documents would pose too much of a burden. As described above, this objection is unsubstantiated and unfounded. Lilly also argues that, since the Plaintiffs do not allege that they consumed Effexor, discovery about communications

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about the drug's withdrawal profile are not relevant. This is not correct. Lilly was marketing Cymbalta against Effexor. How Lilly viewed its competitor's withdrawal profile is directly relevant to whether that view influenced Lilly's decision to put misleading information on the Cymbalta label. By way of example, the Effexor label does not contain any percentage risks associated withdrawal but for some reason the Cymbalta label contains the misleading phrase "greater than or equal to 1%" in describing its withdrawal risk. This request is clearly calculated to lead to admissible evidence and, thus, requires a response. Please supplement with responsive documents within six days of this letter, or Plaintiffs will file an appropriate motion with the Court.

**RFP No. 40**

This request seeks production of documents related to "why the rate of WITHDRAWAL reflected in the PERAHIA article was included with European LABEL." Lilly directs Plaintiffs to two documents from a prior production. However, since the prior production was a priori limited to certain custodians, it is unclear whether the prior production contains all responsive documents. Please certify that no other documents exist or supplement with responsive documents within six days of this letter, or Plaintiffs will file an appropriate motion with the Court.

**RFP No. 42**

Please reproduce in \*.pdf format the document referenced in your response within six days of this letter. The document produced previously was corrupted and is not viewable.

**RFP No. 43**

Please reproduce the documents identified in your response in a Microsoft Excel format within six days of this letter. They are currently produced in 261 separate .tiff images, which is almost impossible to review. The spreadsheets are broken up into different pages, making a uniform review of the document almost impossible in this format. The data is also not subject to sorting in its current format.

**RFP No. 46**

This request seeks a list of all medical professionals "to whom LILLY sent a Medical Information Letter concerning the potential risk of withdrawal or discontinuation from CYMBALTA (e.g., an Excel spreadsheet[])." Lilly refuses to produce this list because the request is not limited to those specific physicians that treated the Plaintiffs. This is disingenuous. First, Lilly agreed to cooperate in allowing Plaintiffs to conduct discovery for all cases at once. Refusing to produce a list that is relevant to all plaintiffs based on objections for a specific plaintiff runs counter to Lilly's promise to this Court and the Judicial Panel on Multidistrict Litigation to allow common discovery for all cases. Second, Lilly argues that it made the full



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withdrawal risks available to physicians upon request of the letter, suggesting that it did not deliberately withhold or mislead physicians with the Cymbalta label. If, as Plaintiffs suspect, this letter went to very few (if any) physicians, then it would rebut Lilly's argument and support Plaintiffs' claim that this approach did not discharge Lilly's duty to warn. Third, Plaintiffs have a right to question the Plaintiffs' physicians about whether they have spoken to anyone on this list about withdrawal and explore whether they learned of any withdrawal risks through professional discussions.

#### **RFP No. 49**

This request seeks production of all documents that reflect Lilly's "involvement in the drafting, editing, and publication [of] the PERAHIA ARTICLE, including but not limited to all email communications, article drafts, and publication plans relating to the PERAHIA ARTICLE." Lilly refuses to produce any responsive documents, arguing that a response would be too burdensome. Lilly directs Plaintiffs to the production of documents in previous litigation suggesting that there might be responsive documents therein. This is not acceptable. All internal communications within Lilly about the publication of the Perahia article are central to this litigation as this is definitive proof that Lilly knew about Cymbalta's actual risks of withdrawal but did not disclose it in its labelling. Refusing to produce these documents is inappropriate, especially when there is no reason why searching for responsive documents would pose any significant burden. The number of people who were involved in the publication of the Perahia article is relatively small. Please supplement with responsive documents within six days of this letter, or Plaintiffs will file an appropriate motion with the Court.

#### **RFP No. 52**

This request seeks documents "reflecting the amount of compensation given to the authors of the PERAHIA ARTICLE[.]" Lilly objects to production of this information as burdensome. This is absurd. Producing documents reflecting the amount of compensation given to a handful of authors is not overly burdensome. Lilly also objects "on behalf of Dr. David Perahia who opposes disclosure of his compensation on privacy grounds." This is a legally unsupportable position. The amount of money that Dr. Perahia, *one* of the authors of the Perahia article, is paid by Lilly goes directly to the credibility of Dr. Perahia and his work. He has been tendered as a witness with relevant information by Lilly, he is employed by Lilly, and he is represented by lawyers representing Lilly. Plaintiffs have every right to evaluate the credibility of his testimony through the lens of how much money Lilly has paid him. Should Dr. Perahia wish to seek a protective order, then a proper motion must be filed. Otherwise, Lilly is under a legal obligation to produce this information and, as it stands, has not complied with that obligation. Please supplement with responsive documents within six days of this letter, or Plaintiffs will file an appropriate motion with the Court.

#### **RFP Nos. 53, 54, 55, and 56**

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These requests all concern the production of documents related to Lilly's past research and development related to Cymbalta and Prozac withdrawal. The requests seek productions of the underlying studies (RFP No. 53), and documents related to those studies and compensation paid to the authors (RFP Nos. 54, 55, and 56). Plaintiffs have a right to conduct discovery into Lilly's research on the withdrawal issue and how it went about evaluating that risk when it possessed a safer medication such as Prozac versus how it went about evaluating that risk with Cymbalta. Lilly issues more boilerplate objections about burden, but does not explain how or why responding to this request would pose any unique burden. This information is relevant and discoverable, and as it stands, Lilly has not provided any response. Please supplement with responsive documents within six days of this letter, or Plaintiffs will file an appropriate motion with the Court.

**RFP No. 64**

Please reproduce the documents identified in your response in a Microsoft Excel format within six days of this letter. They are currently produced in 37,999 separate .tiff images, which is almost impossible to review or organize. The spreadsheets are broken up into different pages, making a uniform review of the document almost impossible in this format. The data is also not subject to sorting in its current format. To the extent that Lilly has redacted certain columns, please simply remove those from the reproduced Excel spreadsheets.

**RFP No. 65**

This request seeks the production of "any agreement with a key opinion leader / thought leader related to CYMBALTA." Lilly refuses to produce these documents because to do so would be burdensome. Producing the signed agreements Lilly uses with medical professionals who are paid to promote Cymbalta should be relatively simple. Lilly undoubtedly has a database where these agreements are stored. Lilly would only need to provide a copy of that database. Lilly also argues that any agreement is irrelevant. This is not true. The fact that Lilly has contracted with thousands of physicians to promote Cymbalta is highly relevant to Lilly's conduct in promoting Cymbalta. That "opinion leaders" were being paid by Lilly to spout positive marketing messages about Cymbalta is important for evaluating whether the medical community was properly apprised of the risks of withdrawal, as Lilly has asserted on multiple occasions. Furthermore, exploring which individuals were under contract will allow Plaintiffs to determine which, if any, physicians were under contract with Lilly that may have consulted with or worked with the physicians that treated the Plaintiffs. This goes to indirect influence that Lilly would have over the Plaintiffs' physicians—also relevant to this case. Please supplement with responsive documents within six days of this letter, or Plaintiffs will file an appropriate motion with the Court.

**RFP No. 73**

This request seeks production of marketing plans, or "brand plans" for Cymbalta. Lilly

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directs Plaintiffs to several brand plans for Cymbalta already produced. Please certify that this production contains all responsive documents. This request was not limited in time, and thus spans the entire product life of Cymbalta from 2003 until the present. Several years of brand plans appear to be missing. Please certify that Lilly possesses no additional brand plans or supplement with responsive documents within six days of this letter, or Plaintiffs will file an appropriate motion with the Court.

**RFP No. 77, 78, and 79**

These requests seek those communications with any third-party about Lilly's direct-to-consumer advertising for Cymbalta. Based on Lilly response to Interrogatory No. 7, the only advertising agency Lilly used for direct-to-consumer advertising was FCB, f/k/a DraftFCB. Thus, this request is tailored to those communications Lilly had with FCB about Cymbalta marketing to consumers. Lilly refuses to produce any documents and only provides boilerplate objections. These are the "over burdensome" variety of objections which, as described above, are without merit. Lilly also directs Plaintiffs to Lilly's prior production, but this is not helpful as there is almost no communications with FCB in the prior productions. Wholly absent from the previous production are communications between Lilly and FCB developing Cymbalta marketing campaigns and whether, if ever, there were any discussions about including withdrawal risks in that marketing. Instead of producing responsive documents, Lilly offers empty objections. Please supplement with responsive documents within six days of this letter, or Plaintiffs will file an appropriate motion with the Court.

**RFP No. 87**

This requests that Lilly disclose those communications it has had with the media relating to Cymbalta withdrawal. These communications will contain admissions by Lilly representatives and are reasonably calculated to lead to admissible information. Lilly, however, refuses to respond to this request, arguing that it is overbroad and burdensome, that these documents are publically available, and that it is duplicative of RFP No. 71. All of these arguments are meritless. First, the burden of searching through emails and correspondence that Lilly has had with reporters about Cymbalta and withdrawal ought to be minimal. Second, email exchanges between Lilly representatives and media outlets are not publicly available. Third, this request seeks more than fully vetted press releases, but specific comments and statements made to the media about Cymbalta and its risk of withdrawal. Thus, all of Lilly's objections are unfounded. As it stands, Lilly's refusal to produce any responsive documents is in violation of the Rules. Please supplement with responsive documents within six days of this letter, or Plaintiffs will file an appropriate motion with the Court.

**RFP No. 92**

This request seeks production of any contracts or agreements that may exist between Lilly and the Plaintiffs' physicians. Lilly refuses to produce these documents arguing that any

J. Bozman  
March 13, 2015  
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contract between Lilly and the Plaintiffs' physicians would not be relevant to this lawsuit. This is absurd. If there are legal agreements between Lilly and the Plaintiffs' physicians, then it goes directly to the credibility of their testimony and whether they would have an incentive to protect a relationship with Lilly. Exploring the contents of any such agreement is entirely within the permissible bound of discovery. As it stands, Lilly's refusal to produce any responsive documents is in violation of the Rules. Please supplement with responsive documents within six days of this letter, or Plaintiffs will file an appropriate motion with the Court.

**RFP No. 96**

This request asks Lilly to produce "all records in YOUR possession related to Plaintiff." Lilly agrees to produce any documents obtained prior to initiating this lawsuit, but refuses to supply any documents acquired afterward. The reason for this is because Plaintiffs would not agree to subsidize Lilly's efforts to collect medical records that *Lilly believes* are relevant to this litigation. This is not a valid ground to withhold production. Plaintiffs have willingly produced all documents in their possession related to their medical treatment. Lilly, however, on its own initiative, has elected to go out and subpoena additional records from various medical providers. In furtherance of that effort, Plaintiffs provided authorizations and complied with Lilly's requests. Nothing obligates Plaintiffs to pay for Lilly's litigation strategy, and Plaintiffs' refusal to share in the costs of collecting those records that *Lilly wants*, does not obviate Lilly's independent obligation to produce documents in its possession that are relevant to this litigation. The suggestion that Lilly is not under an obligation to respond to a valid discovery request because Plaintiffs refused to subsidize Lilly's efforts to collect records is deeply flawed and misapprehends the fact that *Lilly*, not the Plaintiffs, elected to go out and obtain those records. Lilly has a legal obligation to produce those non-privileged documents in its possession that relate to the Plaintiffs. Please advise if Lilly will comply with this request within six days of this letter, or else Plaintiffs will file an appropriate motion with the Court.

Sincerely,

A handwritten signature in black ink, appearing to read "R. Brent Wisner", with a stylized flourish at the end.

R. Brent Wisner, Esq.  
Baum Hedlund Aristei & Goldman, P.C.  
12100 Wilshire Blvd., Suite 950  
Los Angeles, CA 90025  
(310) 207-3233

## Exhibit 8

## COVINGTON & BURLING LLP

BEIJING BRUSSELS LONDON NEW YORK  
SAN DIEGO SAN FRANCISCO SEOUL  
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EMILY ULLMAN

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T 202.662.5662  
eullman@cov.com

November 11, 2014

BY ELECTRONIC MAIL

T. Matthew Leckman  
Pogust Braslow & Millrood LLC  
8 Tower Bridge, Suite 1520  
161 Washington Street  
Conshohocken, PA 19428

Re: Hexum v. Eli Lilly & Co., No. 13-cv-2701 (C.D. Cal.)  
Herrera v. Eli Lilly & Co., No. 13-cv-2702 (C.D. Cal.)

Dear Matt:

In the wake of last week's status conference with Judge Nagle and in response to your October 30 counterproposal, we offer on behalf of Lilly the revised custodial document collection proposal set forth below.

A few initial notes: First, we disagree with the characterization of your requests as "targeted . . . to those individuals and categories of individuals whose custodial files are likely to contain or lead to the discovery of admissible evidence on Cymbalta and discontinuation / withdrawal" based on the 30(b)(6) depositions you have conducted. According to the deposition testimony on which you rely, many of the named employees have responsibilities across multiple or even all Lilly products. We similarly disagree with your characterization of the various committees you purport to identify.

Second, we are now only a month away from the close of fact discovery, and Judge Nagle has denied Plaintiffs' request to extend the discovery deadline. Given the lateness of the request for these custodial files and the depositions of Drs. Hoog and Perahia and Ms. Mescher and in light of the very short discovery period remaining, the scope of Plaintiffs' requests is simply not realistic in the face of the soon-approaching discovery deadline in these cases.

Following is Lilly's response to your October 30 counterproposal.

*Individuals to be Searched:* In light of the above discussion, Lilly believes that its original nine-person list -- David Perahia; Nayan Acharya; Mark Bangs; Greg Brophy; Sharon

## COVINGTON &amp; BURLING LLP

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Hoog; Bryan Boggs; Anne Sakai-Robbins; John Hixon; and Sara Mescher -- is of an appropriate size and covers a reasonable range of topic areas. If you would prefer to substitute one of the other 52 requested custodians for a person on this list, we are open to reasonable discussion , but not to increasing the number.

*Scope of Search:* Again, given the limited time available to Lilly to complete a significant collection, processing, search, and review task, Lilly will search *only* emails in which at least one of the designated individuals appears in at least one of the “To,” “From,” “CC,” or “BCC” fields. Lilly does not intend to collect and search hard-copy documents or individuals’ stored electronic documents. We are willing, however, to drop the date range limitations to which you have objected, and will search emails without a date limitation.

*Search Terms:* After considering your terms proposal and incorporating many of your desired changes, Lilly will use a search string that requires each document to have both a “Cymbalta Term” and a “Discontinuation-Emergent Adverse Event Term” from the list below:

Cymbalta Terms

Cymbalta\*  
cy  
dulo\*

**AND**Discontinuation-Emergent Adverse Events Terms

DEAE\*  
discon\*      and (adverse or symptom\*)  
withd\*      and (adverse or symptom\*)  
taper\*      w/25 (adverse or symptom\*)  
abrupt\*      w/25 (adverse or symptom\*)  
cold      w/1 turkey  
addict\*  
habit\*  
paresth\*  
zaps  
electric      w/4 shock  
Fava  
Rosenbaum  
Schatzberg  
half-life  
downregu\*  
Perahia      w/10 (Affect\* Kajdasz discon\*)

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We note that because several of these search terms are in the Cymbalta label, this search is likely to return significant numbers of otherwise non-responsive documents to which the label is attached. We are formulating a plan to address this concern, but we wanted to flag the issue for you now.

Sincerely,

/s Emily Ullman

Emily Ullman



## Exhibit 9

## COVINGTON

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### BY ELECTRONIC MAIL

March 19, 2015

R. Brent Wisner, Esq.  
Baum Hedlund Aristei & Goldman, P.C.  
12100 Wilshire Blvd., Suite 950  
Los Angeles, CA 90025

**Re: *Hagan-Brown v. Eli Lilly & Co.*, 14-CV-1614 (E.D. Va.)  
*Ali v. Eli Lilly & Co.*, 14-CV-1615 (E.D. Va.)**

Dear Mr. Wisner:

I write in response to your letters dated March 13, 2015 and to follow up after the parties' telephonic meet-and-confer on March 17, 2015 concerning Lilly's responses to Plaintiffs' First Set of Requests for Production ("RFPs"), First Set of Interrogatories, and Amended First Set of Requests for Admission ("RFAs"). Lilly stands by its objections to many of Plaintiffs' discovery requests and maintains that much of the information Plaintiffs seek is contained in Lilly's existing substantial production. However, in order to facilitate discovery on the expedited schedule in this Court and minimize motions practice, Lilly provides the following information regarding certain responses per the parties' discussion during the meet-and-confer. Lilly hopes that the parties will be able to reach a compromise on other outstanding issues. This letter addresses the RFPs first, followed by the Interrogatories and the RFAs.

As a preliminary matter, with the exception of requests for which Lilly stands on its objections, Lilly will produce all remaining responsive documents and provide any outstanding responses by April 3, 2015. Although Lilly will provide the majority of these documents and responses to Plaintiffs next week, if Lilly collects and produces the emails of two additional custodians and/or additional documents related to Plaintiffs' design defect claim, as suggested during the meet-and-confer, that process may take longer, hence the April 3, 2015 deadline.

### **I. Requests for Production**

#### Custodian Issues (RFP Nos. 13, 24, 25, 26, 35, 36, 39, 41)

Lilly understands that the parties have a tentative agreement that Lilly will collect documents from two additional Lilly employees named by Plaintiffs that are responsive to certain search terms. Lilly notes that Plaintiffs have not yet confirmed the two additional custodians for collection. Beyond this agreement, the parties have a continued dispute concerning other custodians, which relates to these Requests.

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### RFP No. 2

Lilly has confirmed that documents representing the Summary Basis of Approval (“SBA”) are publicly available on Drugs@FDA for most Cymbalta indications. As you may know, FDA is no longer required to write a SBA and often satisfies its requirement to publicly disclose its approval basis not with a single SBA document but by posting key documents from the NDA approval package on its website. These approval package documents are publicly available for the Cymbalta indications listed below. As for the GAD indications, they are not on the FDA website, and Lilly is investigating whether it has copies of the approval package documents and if so, whether they have been previously produced. Contrary to your representation, the document you cite shows that in 2008 Lilly did *not* have these documents related to the GAD approval readily available and had reached out to FDA for help due to the difficulty in obtaining these documents. See CYM-01510972; CYM-01510975.

#### MDD (NDA 21-427):

[http://www.accessdata.fda.gov/drugsatfda\\_docs/nda/2004/021427\\_s000\\_Cymbalta.cfm](http://www.accessdata.fda.gov/drugsatfda_docs/nda/2004/021427_s000_Cymbalta.cfm)

#### DPNP (NDA 21-733):

[http://www.accessdata.fda.gov/drugsatfda\\_docs/nda/2004/021733s000\\_CymbaltaTOC.cfm](http://www.accessdata.fda.gov/drugsatfda_docs/nda/2004/021733s000_CymbaltaTOC.cfm)

#### MDD Maintenance Therapy (sNDA 21-427, S-015):

[http://www.accessdata.fda.gov/drugsatfda\\_docs/nda/2007/021427Orig1s015\\_s017.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/nda/2007/021427Orig1s015_s017.pdf)

#### Fibromyalgia (NDA 22-148):

[http://www.accessdata.fda.gov/drugsatfda\\_docs/nda/2008/022148\\_cymbalta\\_toc.cfm](http://www.accessdata.fda.gov/drugsatfda_docs/nda/2008/022148_cymbalta_toc.cfm)

#### Chronic Musculoskeletal Pain (NDA 22-516):

[http://www.accessdata.fda.gov/drugsatfda\\_docs/nda/2010/022516\\_cymbalta\\_tocEDT.cfm](http://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022516_cymbalta_tocEDT.cfm)

### RFP Nos. 23, 43, 64

Plaintiffs have asked for Excel file versions of certain documents responsive to these requests. The document of LSS data responsive to RFP No. 23 is not a native Excel file and was provided to us in PDF format, which we have sent to you. Otherwise, we have provided the other requested files in Excel format.

### RFP Nos. 30, 31, 32, 33

Lilly is investigating doing targeted searches of collections of documents or emails from the Global Patient Safety division or another relevant department to produce documents related to the development of a 20 mg dose of Cymbalta, and the consideration, if any, of lower doses.

### RFP No. 38

Lilly previously searched for the minutes of various committees related to Cymbalta, including the Periodic Safety Review Committee, the Safety Surveillance Team, and the G10 Team, and produced the fruits of this search along with other committee related materials in

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December 2014. The Excel attachment to this letter lists the Bates numbers corresponding to these documents (714 documents total).

### RFP No. 42

Plaintiffs have asked for a PDF version of the document responsive to this request to replace a corrupted file. This has been sent to you.

### RFP No. 46

Lilly objected to this request because the names of medical providers not involved in this litigation are not relevant. Furthermore, if any medical information letters relating to Cymbalta and discontinuation symptoms were sent by Lilly to the doctors involved in this litigation, or other similar pending actions, they will be captured by Plaintiffs' other documents requests. As a compromise, Plaintiffs agreed to accept information about the number of doctors who were sent Lilly's medical information letter about Cymbalta and discontinuation symptoms. Lilly responds that from September 2006 to September 2013, Lilly sent its medical information letter on Cymbalta discontinuation symptoms to 1,072 health care professionals.

### RFP No. 73

Lilly confirms that the brand plans produced to Plaintiffs are all the Cymbalta brand plans that Lilly was able to locate through multiple diligent searches. Nevertheless, in response to your inquiry, we are investigating whether we can identify earlier plans.

## **II. Interrogatories**

### Interrogatory No. 2

Although Lilly maintains its objection that identifying every current and former employee who worked on Cymbalta in the ten listed departments is unreasonably burdensome and nearly impossible, Lilly is in the process of gathering additional names in each department to provide to Plaintiffs. Lilly notes that many of these individuals can be identified from the correspondence contained in Lilly's existing production and from its three 30(b)(6) depositions. Lilly notes that Exhibit 2 to the 30(b)(6) deposition of Elyas Musleh and Exhibit 2 to the 30(b)(6) deposition of Stephen Knowles collectively list 43 current and former Lilly employees whose names are responsive to this Interrogatory.

### Interrogatories Nos. 4, 5

The documents cited in Lilly's responses are the complete records responsive to these Interrogatories (and RFP No. 64) from the beginning of the Cymbalta product line to 2013. The charts at CYM-02777128 - CYM-02777355 present information about non-employee doctors associated with Lilly relating to Cymbalta from 2004 to 2005, and those at CYM-02739356 - CYM-02743863 present the information in a slightly different format from 2006 to 2013. The other documents, CYM-02743864 - CYM-02777127, contain information about the activities of these individuals between 2004 and 2013.

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Interrogatories Nos. 6, 8, 9

Lilly is investigating which vendors, if any, were involved in the activities described in these Interrogatories, to the extent it is feasible to determine.

Interrogatories Nos. 18-20

Lilly's production of publication plans is forthcoming, which we believe satisfies these Interrogatories as to journal publications relating to Cymbalta. As for articles relating to other products, Lilly stands on its objections.

**III. Requests for Admission**

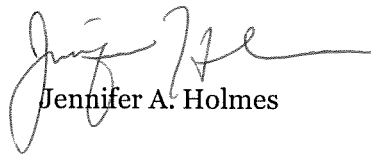
RFA No. 29

Lilly is continuing to investigate the extent to which the Perahia article or the information contained therein was provided to sales representatives for distribution to medical professionals and will provide Plaintiffs with a response next week.

\* \* \*

It is Lilly's understanding that for the remaining requests discussed in Plaintiffs' letters, either the parties came to an agreement during the call or the parties have reached an impasse at this time. There are also some requests that may be on hold for further consideration by Plaintiffs.

Sincerely,



Jennifer A. Holmes

## Exhibit 10

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March 19, 2015

BY ELECTRONIC MAIL

Michael Imbroscio  
Covington & Burling LLP  
One City Center  
850 Tenth Street, N.W.  
Washington, D.C. 20001

Re: *Hagan-Brown v. Eli Lilly and Company*, 14-CV-1614 (E.D. Va.)  
*Ali v. Eli Lilly and Company*, 14-CV-1615 (E.D. Va.)  
**Lilly's Internal Communications Production Plan**

Dear Mr. Imbroscio,

This letter is to follow up on our lengthy meet-and-confer on Tuesday, March 17, 2015. Based on our discussion, I understand that Lilly does not have the ability to search the emails of all 30,000+ employees at Lilly in a single search. Instead, to search for emails, specific "custodians" need to be identified first. As it stands, based on a letter that your office sent to my co-counsel Mr. Matt Leckman on November 11, 2014, Lilly has produced documents relating to nine custodians: David Perahia, Nayan Acharya, Mark Bangs, Greg Brophy, Sharon Hoog, Bryan Boggs, Anne Sakai-Robbins, John Hixon, and Sara Mescher. Based on that letter, emails were produced that contained any of these custodians in the "To," "From," "CC," or "BCC" fields and specified search terms.

During our call, I stated that we had a running list of additional custodians whose emails likely contain relevant information about Cymbalta withdrawal. I estimated that the list contained over a hundred names. You stated that Lilly would not be willing or capable of searching through that many email accounts within the accelerated discovery schedule imposed by this Court. You stated that Lilly would be willing to search, at most, two additional custodian files. I said Plaintiffs would accept those two additional custodian files but would file a motion on rest of the custodians.

I want to be clear—I do not believe Lilly is entitled to seek refuge in the fact that there is insufficient time for Lilly to comply with Plaintiffs' valid discovery requests. Plaintiffs were clear at the initial status conference that Plaintiffs would require a significant amount of additional discovery. Lilly did not request any additional time from the Court, nor did Lilly

M. Imbroscio  
March 19, 2015  
Page 2

support Plaintiffs' effort to obtain additional time. Then, when Plaintiffs' moved to transfer these cases to a centralized proceeding in the Southern District of Indiana, Lilly opposed. The Court held that it would defer ruling on the motion to transfer pending completion of discovery in this case. The Court reasoned:

On-going discovery in this District will provide an opportunity on a relatively expedited basis to complete discovery **on common issues that will be useable in all Cymbalta withdrawal cases** and for that reason will contribute to the efficient case management of those cases.

*Ali v. Eli Lilly and Company*, 1:14-cv-1615-AJT-JFA, slip op. at 9 (E.D. Va. Mar. 4, 2015) (emphasis added). In other words, Lilly demanded to stay in this Court, so it will have to comply with the Court's expedited discovery schedule.

In anticipation of the Plaintiffs' motion to compel, I wanted to outline the proposal that Plaintiffs' will seek to compel. Should this proposal influence Lilly's position regarding the production of internal emails please advise immediately. I plan to file a motion by tomorrow.

### **Production of Lilly's Internal Discussions about Cymbalta Withdrawal**

#### **A. Relevant Custodians:**

The following are the custodians Plaintiffs identified that likely have relevant emails. They have been ordered into three tiers of custodians.

#### *Tier One (31 total)*

Based on a review of the documents produced so far, these individuals were either senior Lilly personnel who were involved in discussions about Cymbalta and its withdrawal effects and / or individuals who discussed issues related to Cymbalta withdrawal in emails already produced.

Andrew Buchanan	John M. Plewes	Richard Bump
Angela Wade	Louise M. Spruce	Steve Sugino
Antonio Stefano Crucitti	Madelaine M. Wohleisch*	Steven Knowles
Beatrice Grimault	Marcia Vowles	Susan G. Ball
Carol H. Stephens	Matt Kuntz**	Tim Garnett
Carole Boylan	Melissa J. Joliat	Timothy M. Conrad
D. Mark Gapinski	Michael Detke*	Torkil Fredborg
Daniel K. Kajdasz	Michael J. Robinson	Virginia L. Wyss
Durisala Desai	Michael P. Roesner	William G. Losin
Joe Wernicke	Patrizia Cavazzoni	
Joel Raskin	Phyllis Barkman Ferrell	



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*\* Are the individuals that Plaintiffs would like emails from as part of Lilly's offer to conduct two custodian searches for this case.*

*\*\* Matt Kuntz was identified as a person with relevant information in Lilly's response to Plaintiff's Interrogatory No. 1.*

*Tier Two (46 total)*

Based on a review of the documents produced so far, these individuals communicated with other individuals within Lilly about Cymbalta withdrawal or the design of the Cymbalta capsule.

Alberto Liedo	Indiana Strombom	Natalie DiPietro
Ana Garcia-Cebrian	James L. Gahimer	Peter R. Bieck
Apurva Prakash	James M. Russell	Pierre V. Tran
Arie Regev	Jeanette S. Deem	Rachel L. Wallace
Ashraff A. Rampersaud	Jeffery Ferguson	Robbin Pitts Wojcieski
Beth Pangallo	Jill C. Chappell	Robert W. Baker
Carrie Young	Joachim Wernicke	Shannon C. Tatom
Charles M. Beasley Jr.	Juliet E. Maclean	Stephanie de Bono
Cherri Miner	Kimberly Spencer	Susanne Lee
Curtis G. Wiltse	Lars Viktrup	Teresa L. Cotton Santos
Danielle Rodgers	Lise Soerensen	Timothy J. Edison
David K. Records	Margaret Ferguson	Vitali Pool
Diane Mackleston	Mary E. Nilsson	Walter Deberdt
Doug Williamson	Melissa J. Ossanna	Yili Lu
Eric Baclet	Michele Sharp	
Fujun Wang	Na Cai	

*Tier 3 (58 total)*

Based on a review of the documents produced so far, these are individuals who were involved in emails related to Cymbalta risks and safety.

Anders Rusten	James P. Leeds	Olubunmi Oduwole
Ann Gibson	Janet Ford	Par Svanborg
Barbara Walsh Brown	Jennifer Ann Zimmer	Patrick K. Brady
Brian Regele	Jennifer Hutchison	Paula Reck
Carole M. Hosford	Joanna Caley	Rania Abdelbarr
Christopher J. Nosek	John G. Watkin	Raul Stucchi
Clare Houk	Jose F. Gomez	Robin R. Deaton
Cora R. Sexton	Julian S. Harrison	S. Bret Paulson
David C. Ceryak	Karen Van Zee	Samuel J. Gardner

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March 19, 2015  
Page 4

David S. Small	Katherine M. Mybeck	Sonja Bragg
Debbie Patterson	Kathleen Bochenek	Stefan Schwoch
Deborah Amann Sissons	Katrien Debruyckere	Stephen Brannan
Delinda E. Kindig	Kirk Russell Hunt	Susan Belanger
Doug Ponsler	Lee C. Byers	Susan Mahony
Eric David Johnson	Lois Kukulewicz	Todd Mason
Ernie Anand	Matt Eggers	Tonya Quinlan
Fanny Verspeelt	Michelle Sangeleer	Valerie Simmons
Graig H. Mallinckrodt	Nancy Jean Trapp	Victoria Cairns
Inmaculada Gilaberte	Ole Kristian Kleivenes	
Jalpa Patel	Oleg V. Martynov	

B. The Search Terms

Previously Lilly created two categories of search terms, “Cymbalta Terms” and “Discontinuation-Emergent Adverse Event Term.” For the purposes of this production, Plaintiffs have modified those search strings.

*Cymbalta Terms*

Cym\*  
Cy  
Dulo\*  
DLX

*Discontinuation-Emergent Adverse Event Terms*

DEAE\*  
DESS\* (note: stands for Discontinuation Emergent Signs and Symptoms)  
TEAE\* (note: stands for Taper-Emergent Adverse Events)  
discon\*  
withd\*  
taper\*  
half-life  
t1/2 (note: term used with reference to half-life)  
paresth\*  
downregu\*  
down w/1 regu\*

C. The Search

1. Lilly will compile all emails in which one of the custodians identified above appear in at least one of the “To,” “From,” “CC,” or “BCC” fields.

M. Imbroscio  
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2. This compilation of emails will not be limited in time.
3. Lilly will then run a search within the bodies (not attachments) of these emails for any documents that contain both a "Cymbalta Term" and a "Discontinuation-Emergent Adverse Event Term."
4. Lilly will produce all responsive emails *and* their attachments, even if the attachment does not contain both a Cymbalta and/or Discontinuation-Emergent Adverse Event Term.
5. Lilly will only redact for privilege, to obliterate personal information such as social security numbers, personal phone numbers and addresses, or obliterate private medical information protected from disclosure by law. Lilly will not be required to produce a privilege log for redactions provided the "to," "from," "cc," "bcc," *and* "subject" fields remain unredacted, and the reason for the redaction appears on the document. Otherwise, Lilly must include any redacted document on a privilege log pursuant to Fed. R. Civ. P. 26(b)(5). No document should be redacted without explanation, as was done in Lilly's prior productions, unless it is included on a privilege log pursuant to Fed. R. Civ. P. 26(b)(5).
6. Concurrently with Lilly's production, Lilly will produce a privilege log.
7. In light of the very stringent discovery timeline in this case, Lilly will provide responsive documents with fourteen days.

Sincerely,

A handwritten signature in black ink, appearing to read "R. Brent Wisner", with a stylized flourish at the end.

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